2003/04 Report Card for the Ontario Drug Benefit Program

Ontario

Drug Program Branch Mandate

- To develop and manage drug programs to ensure that optimal pharmaceutical services are provided for the protection and improvement of Ontarians' health.
- To manage a reimbursement system for prescription drugs.

Strategic Goals

- To ensure on-going access to cost-effective drug therapies through the recommendations of the Drug Quality and Therapeutics Committee (DQTC) and innovative management approaches;
- To manage pharmaceutical expenditures under ODB and present options for new program features and future program designs;

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Strategic Goals

- To promote optimal drug therapy through the development and use of therapeutic guidelines and other evidence-based approaches;
- To maintain a high level of performance of the Health Network System which adjudicates claims;
- To maintain strong working relationships with other governments, drug manufacturers, pharmacists, physicians, third-party insurers, and consumers;
- To provide information to health care professionals and consumers about the ODB program.

Strategic Goals

- To make effective and efficient use of human, financial and technological resources in order to meet program objectives;
- To provide effective and efficient customer service to all our clients;
- To monitor ODB program performance through measures of efficiency, effectiveness and customer satisfaction.

Growth Factors

- newer and more expensive drugs;
- aging population;
- new clinical evidence (indications) and better treatment outcomes involving drug therapy;
- new diseases and new areas of pharmacology;
- increased utilization;
- restructuring of health system (shift to outpatient care);
- continued pressure for manufacturers to increase market share

Report Card Framework

I. Program Overview

Program overview and utilization trends

II. Financial

Financial indicators and cost trends

III. Formulary Listings

Process and Type of Listing

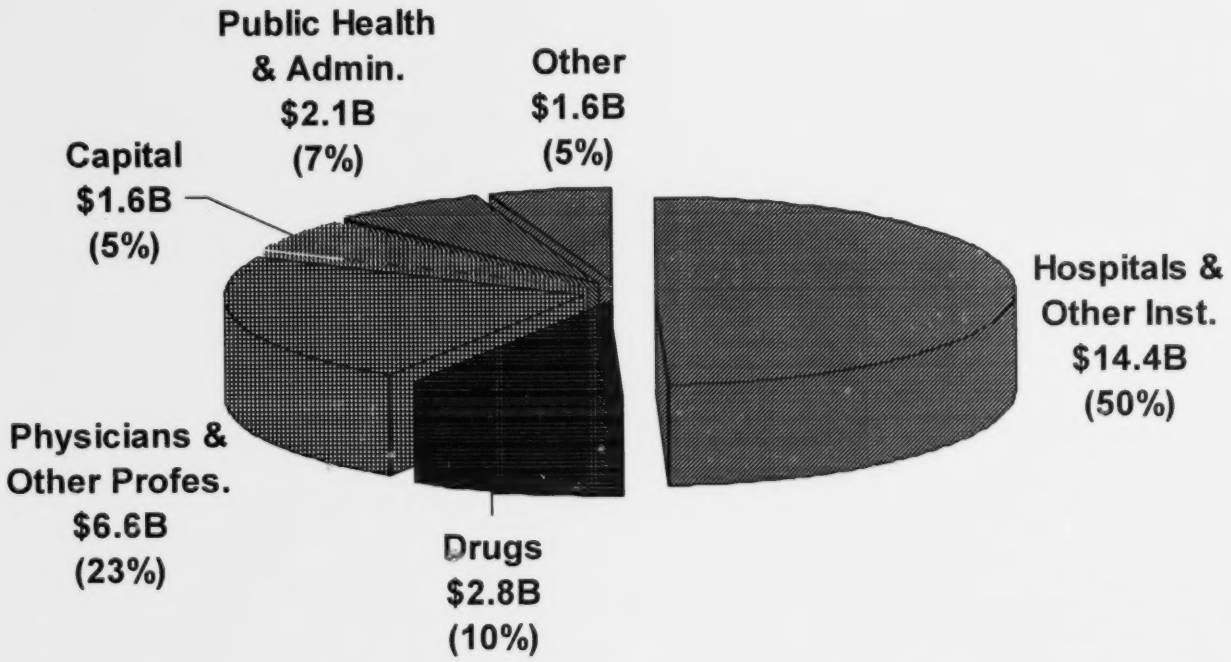
IV. Achievements

Accomplishments and Looking Ahead

Definitions

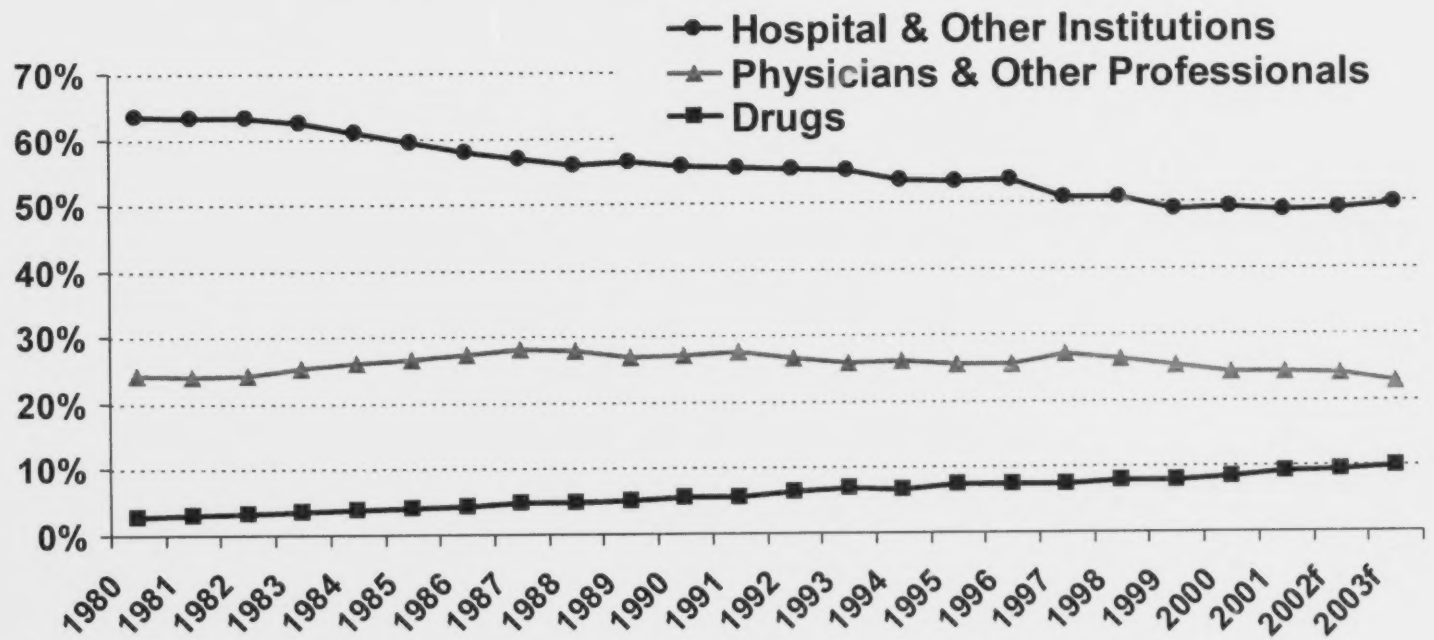
- Beneficiary
  - Eligible person who had at least one claim during the fiscal year.
- Claim
  - Every time a pharmacist fills a prescription, initial or refill.
- Figures include MOHLTC and MCSS programs unless otherwise specified.

Provincial Health Expenditures
Ontario, 2003


Public Health & Admin. $2.1B (7%)
Other $1.6B (5%)
Capital $1.6B (5%)
Hospitals & Other Inst. $14.4B (50%)
Physicians & Other Profes. $6.6B (23%)
Drugs $2.8B (10%)

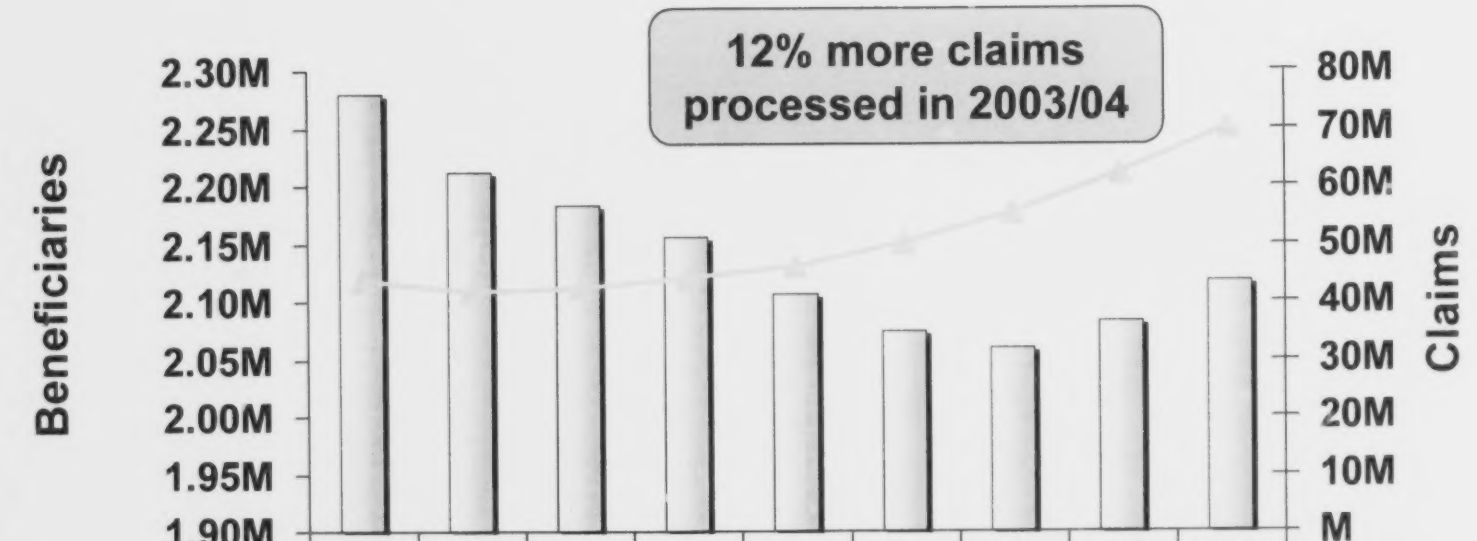
Source: Forecast from the Canadian Institute for Health Information, 2004

Provincial Health Expenditures
Ontario, 1980-2003



Source: Actual and forecasted data from the Canadian Institute for Health Information, 2004

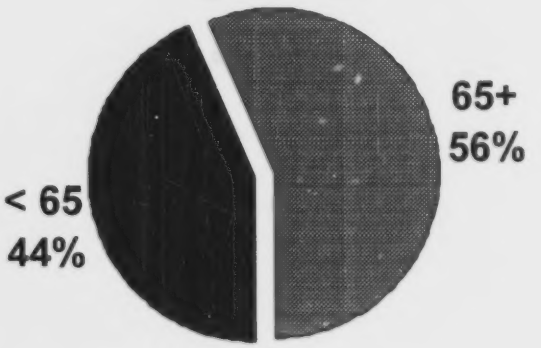
ODB Beneficiaries & Claims
1995/96-2003/04



	95/96	96/97	97/98	98/99	99/00	00/01	01/02	02/03	03/04
Beneficiaries	2.28M	2.21M	2.18M	2.15M	2.11M	2.07M	2.06M	2.08M	2.12M
Claims	43.7M	41.7M	42.3M	44.0M	46.1M	50.0M	55.3M	62.3M	70.0M

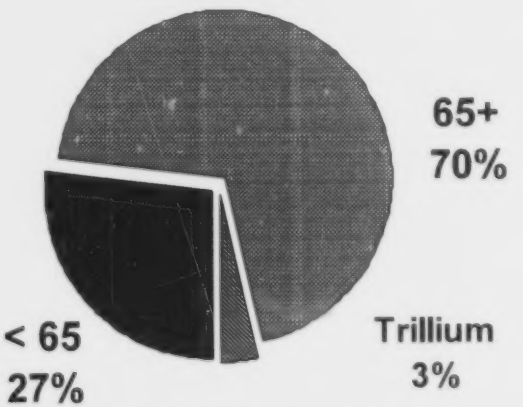
Age Breakdown of ODB Beneficiaries, 1993/94 & 2003/04

1993/94



<65	965K
65+	1,245K
Total	2,210K

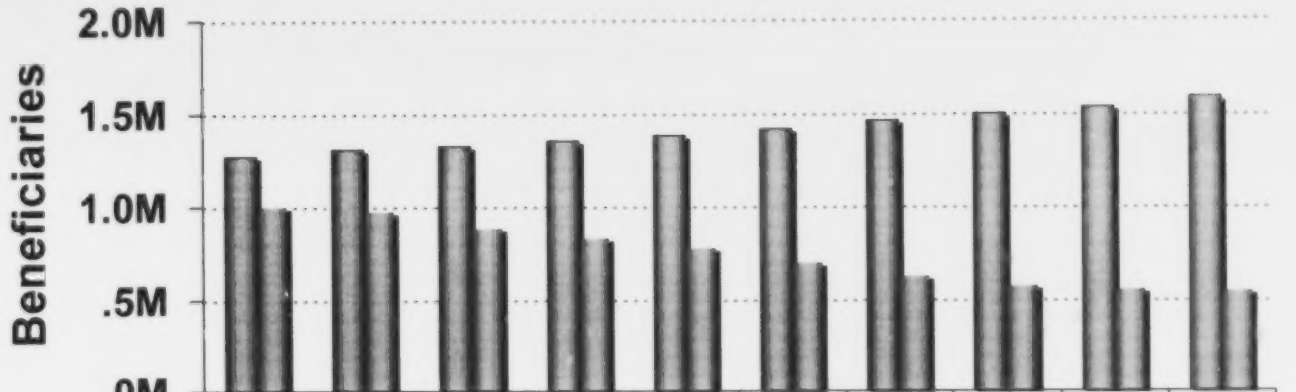
2003/04



<65	572K
Trillium	74K
65+	1,472K
Total	2,118K

Excludes Trillium pre-registration.

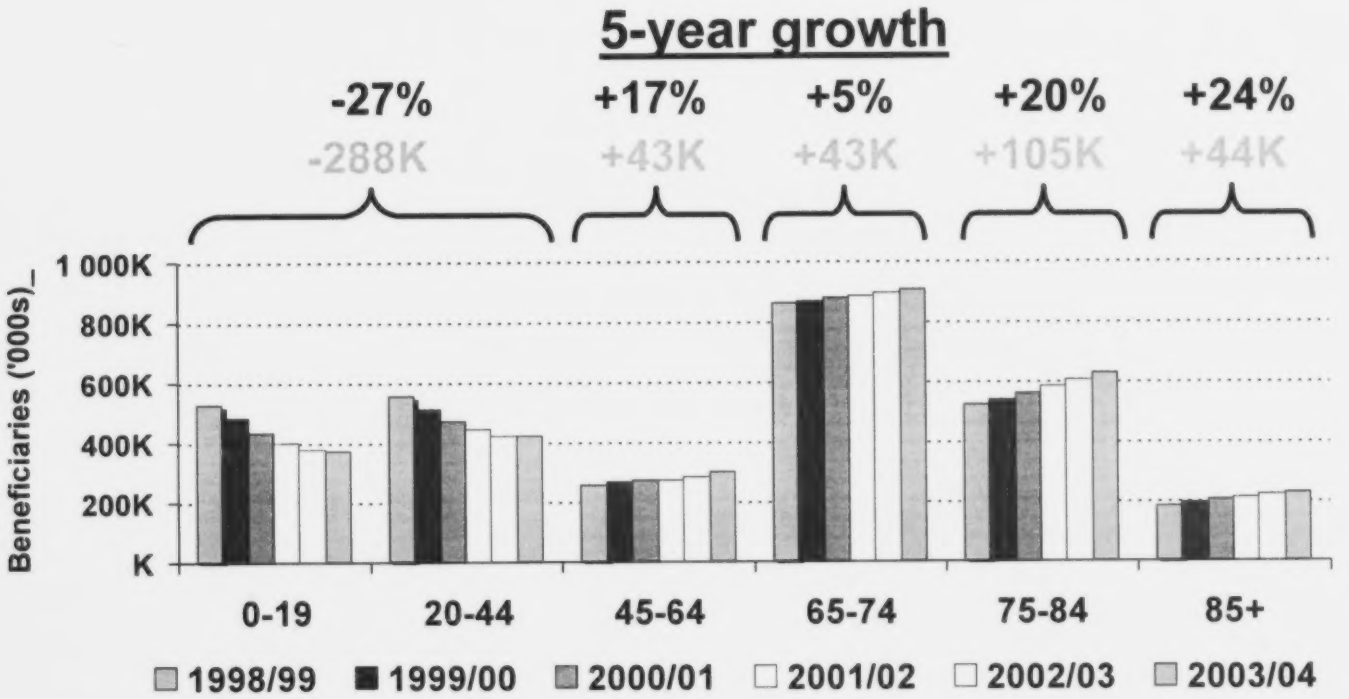
ODB Beneficiaries by Source of Finance, 1994/95-2003/04



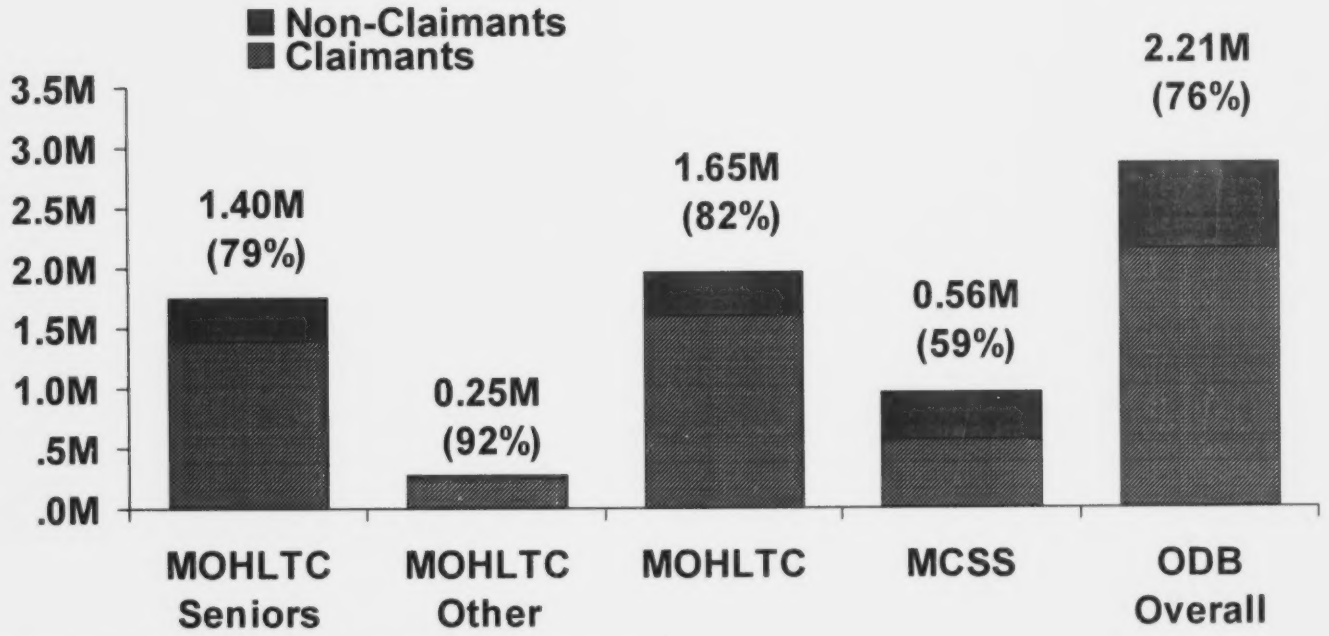
	94/95	95/96	96/97	97/98	98/99	99/00	00/01	01/02	02/03	03/04
MOHLTC	1.27M	1.31M	1.33M	1.35M	1.38M	1.41M	1.46M	1.49M	1.53M	1.58M
MCSS	1.00M	0.97M	0.89M	0.83M	0.78M	0.69M	0.62M	0.56M	0.55M	0.54M

From 1994/95 to 2003/04, the total number of beneficiaries decreased by 7%.

Age Distribution of Eligible Beneficiaries, 1998/99-2003/04

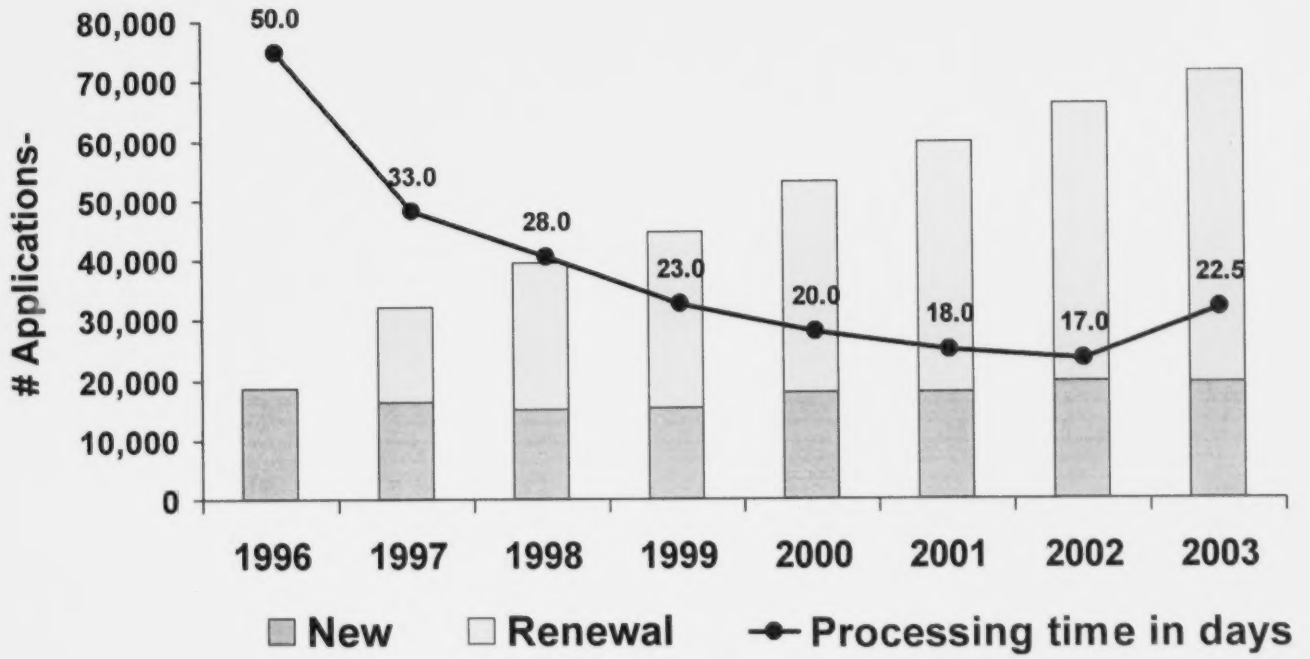


ODB Beneficiaries by Program, 2003/04

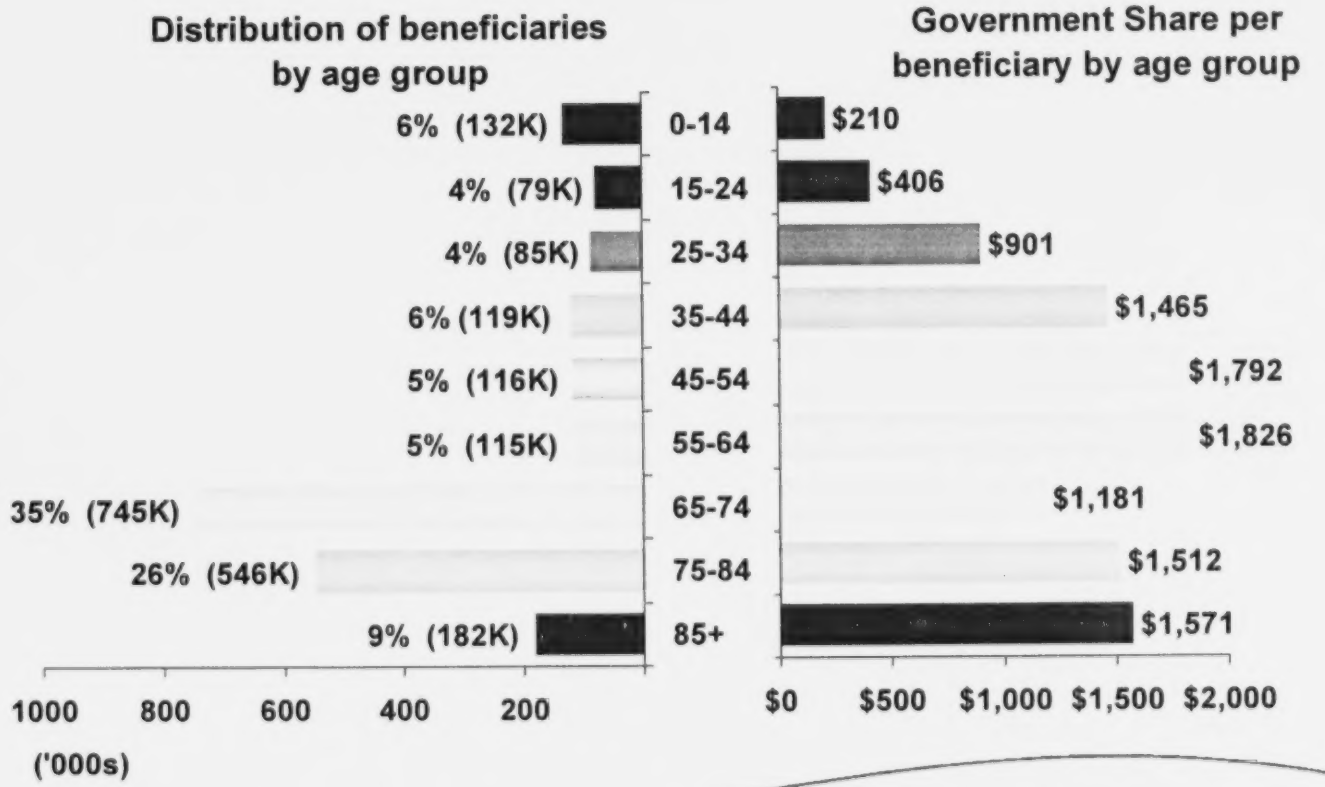


Labels are the number of active beneficiaries and their percentage of the total.

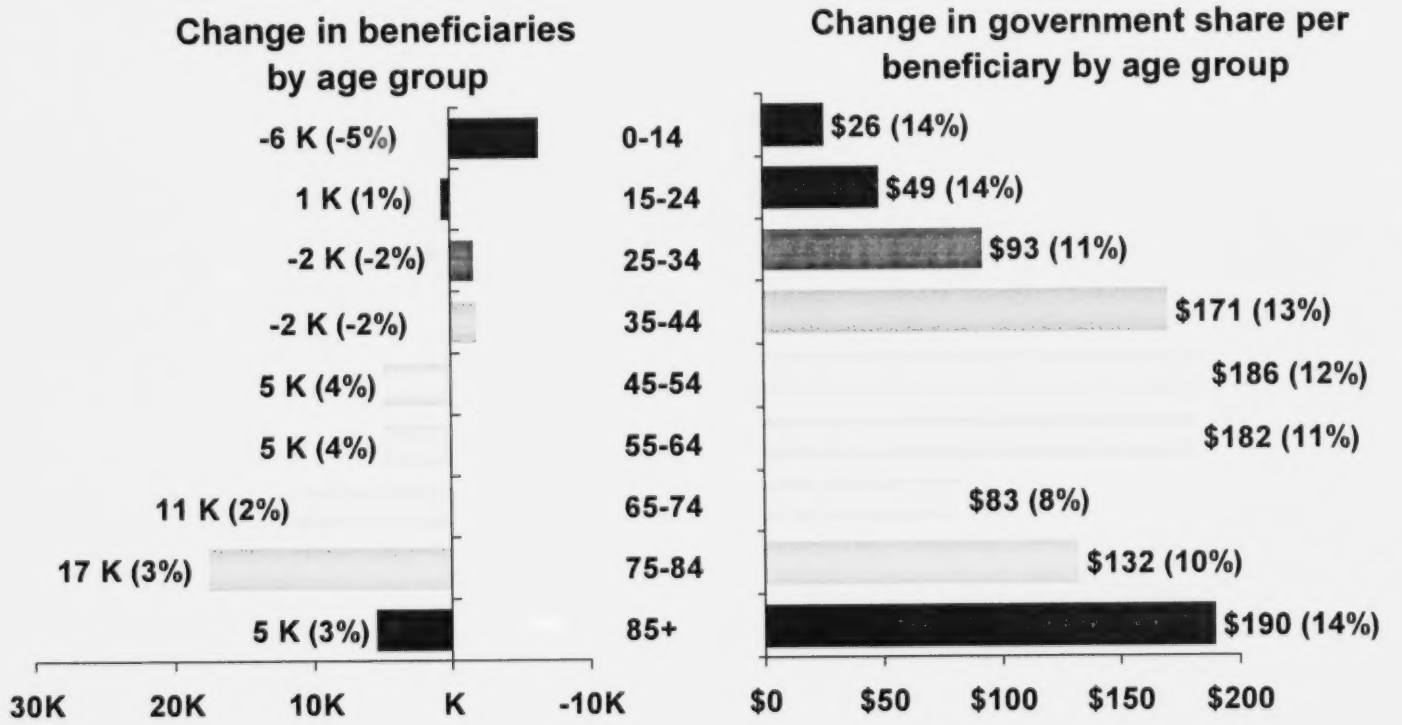
Trillium Applications & Processing Time, 1996 – 2003



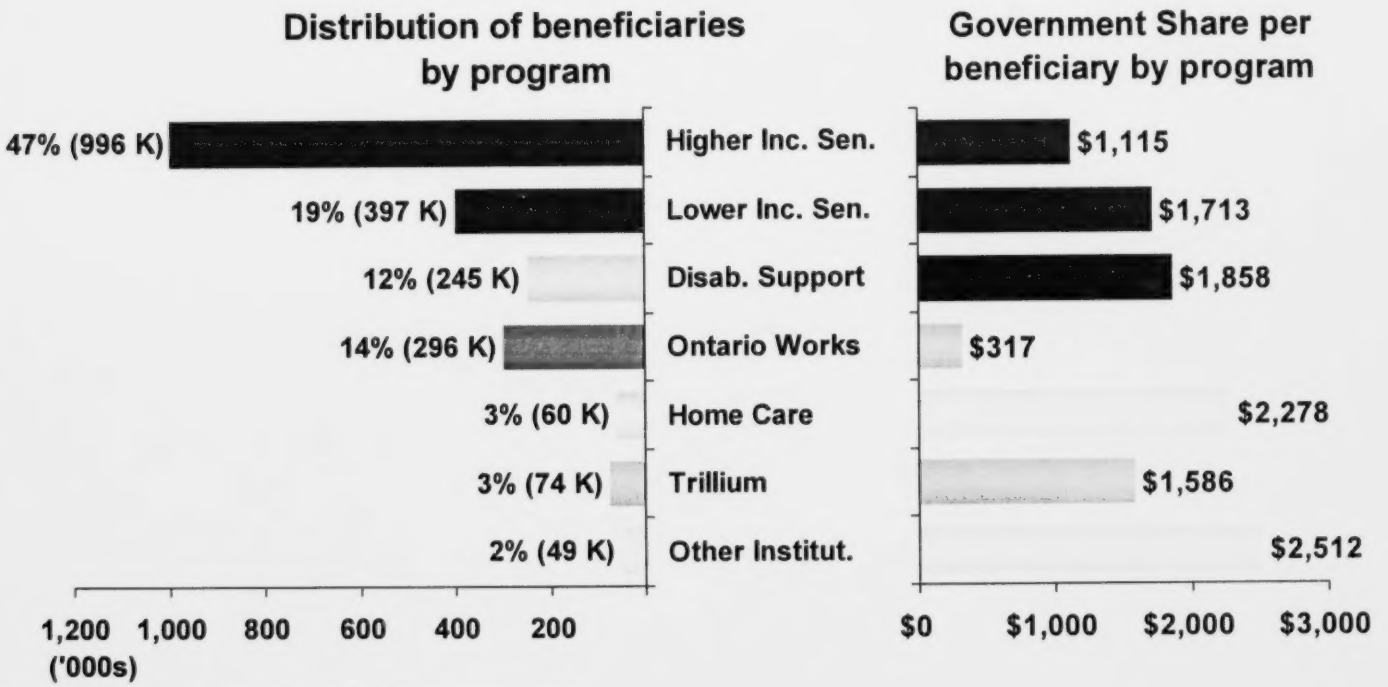
Beneficiary Distribution & Government Share by Age, 2003/04



Change in Beneficiaries & Government Share, by Age, 2002/03-2003/04

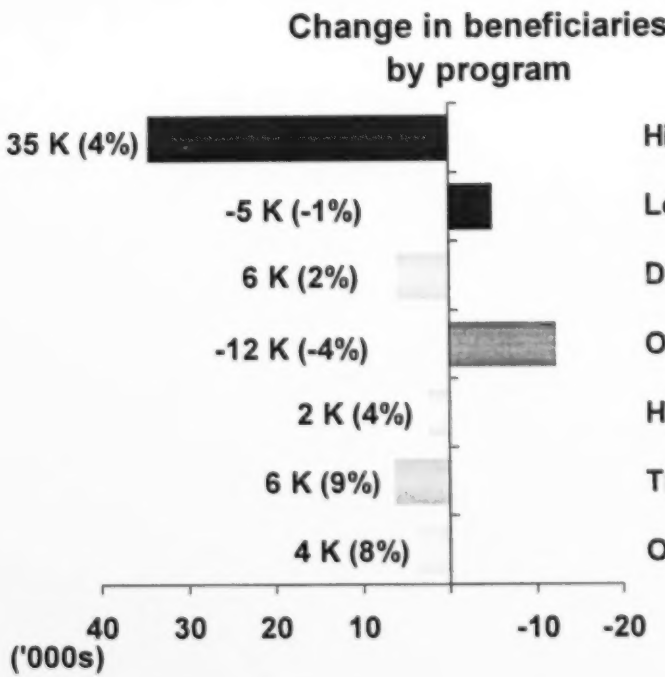


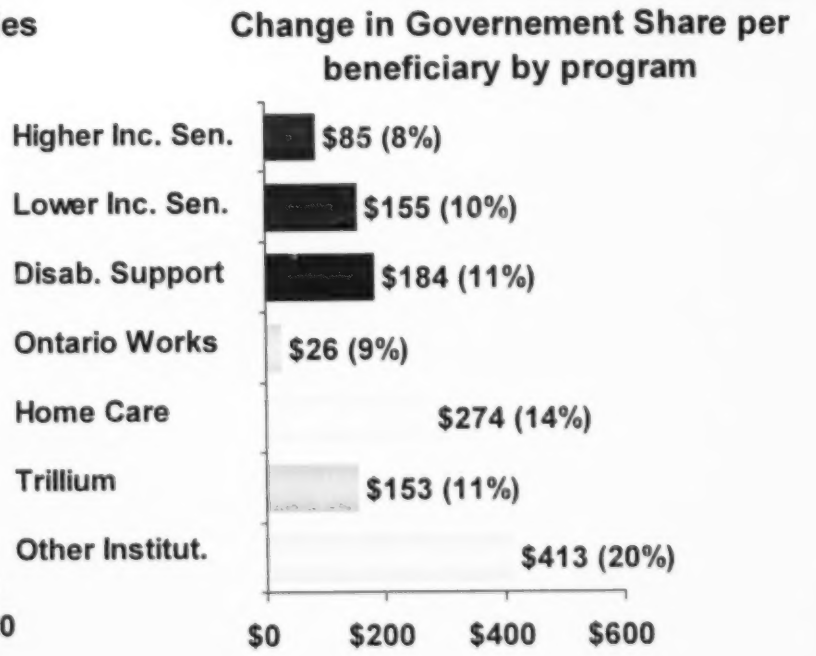
Beneficiary Distribution & Government Share by Program, 2003/04



Note : Other Institutions stands for Special Care and Long-Term Care.

Change in Beneficiaries & Government Share by Program, 2002/03-2003/04





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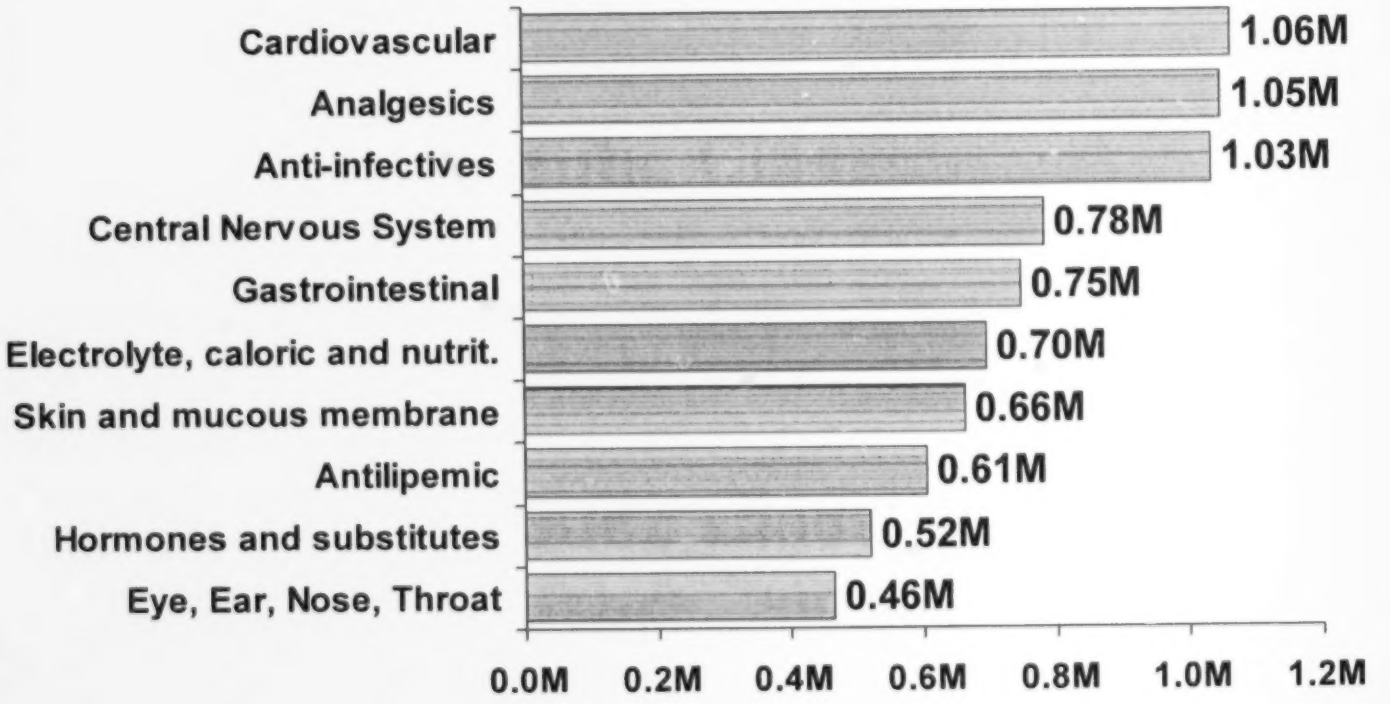
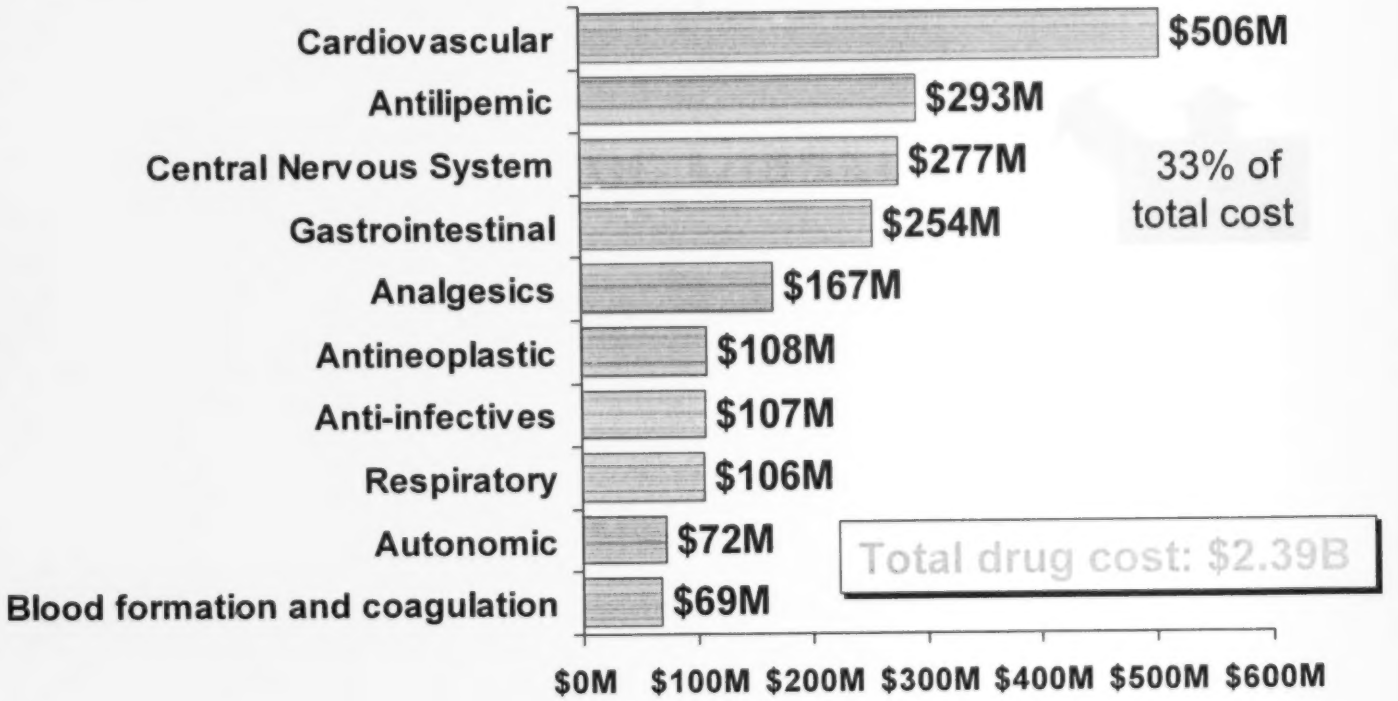
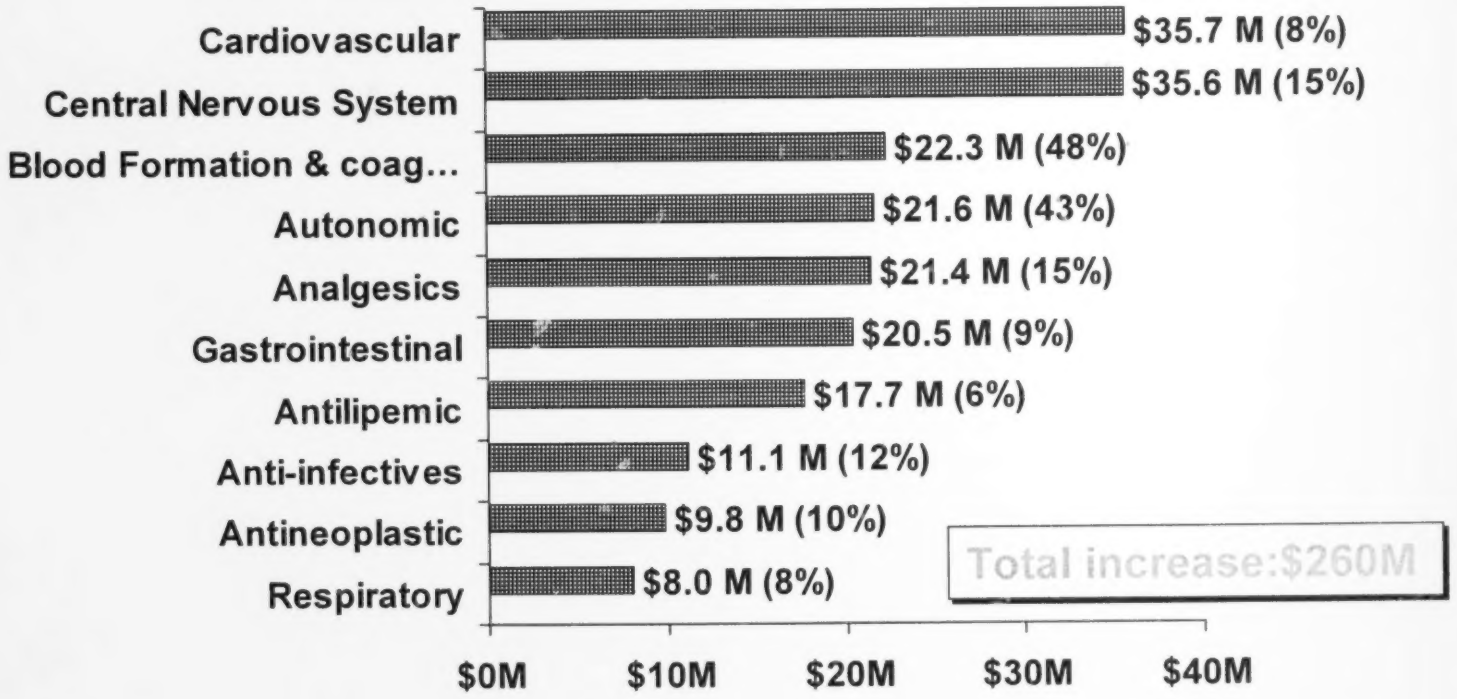
Top-10 Therapeutic Classes by Number of Users, 2003/04



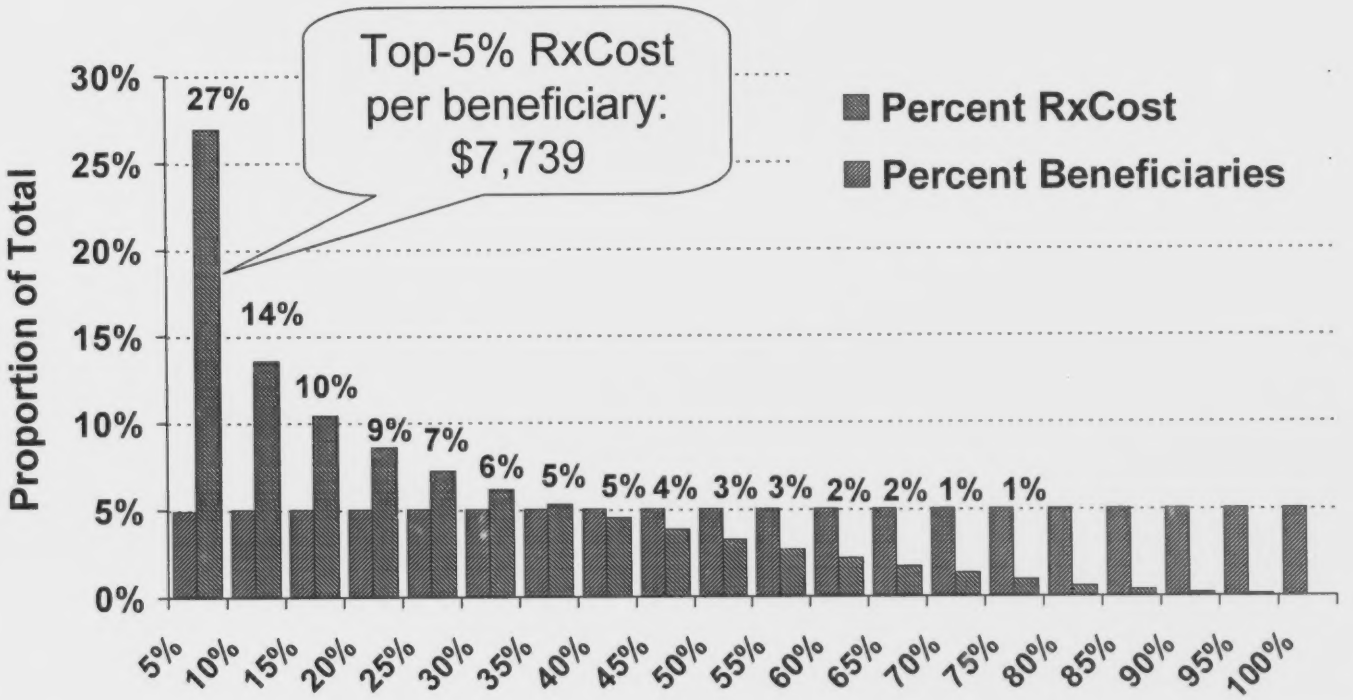
Top-10 Therapeutic Classes by Drug Cost, 2003/04



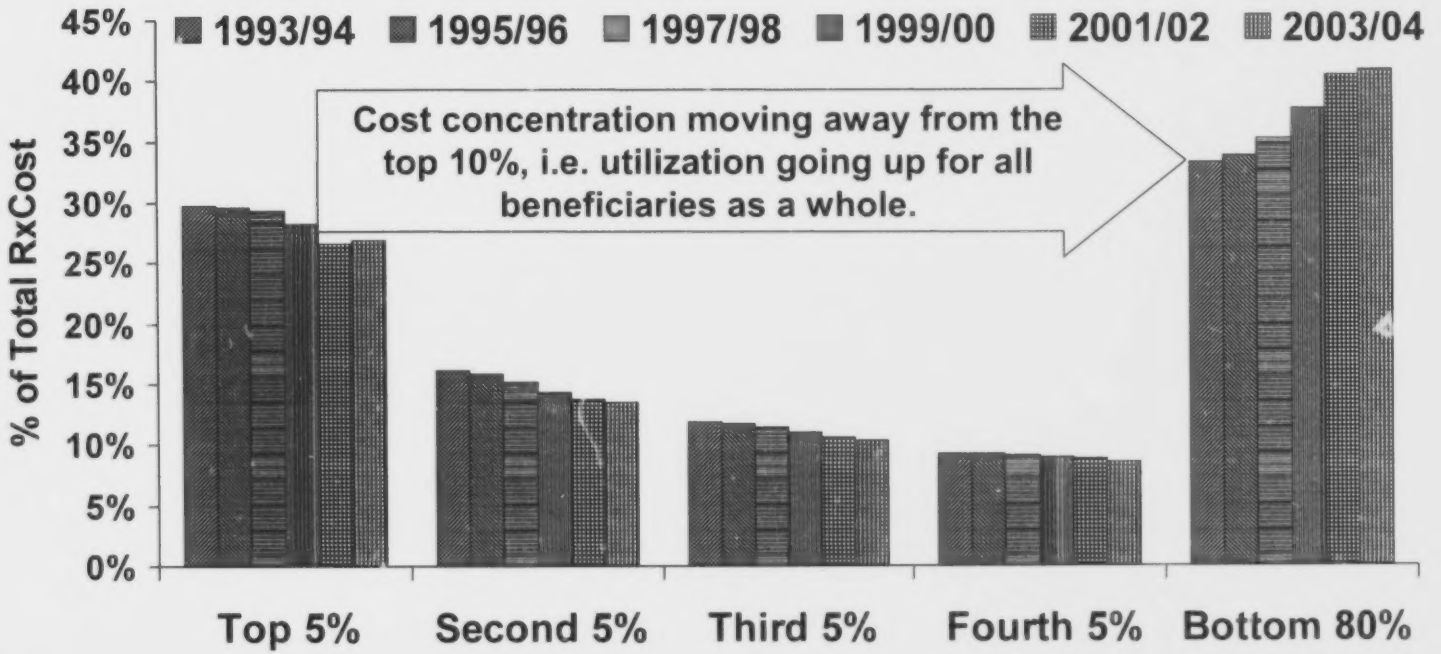
Fastest Growing Classes by Drug Cost, 2002/03-2003/04



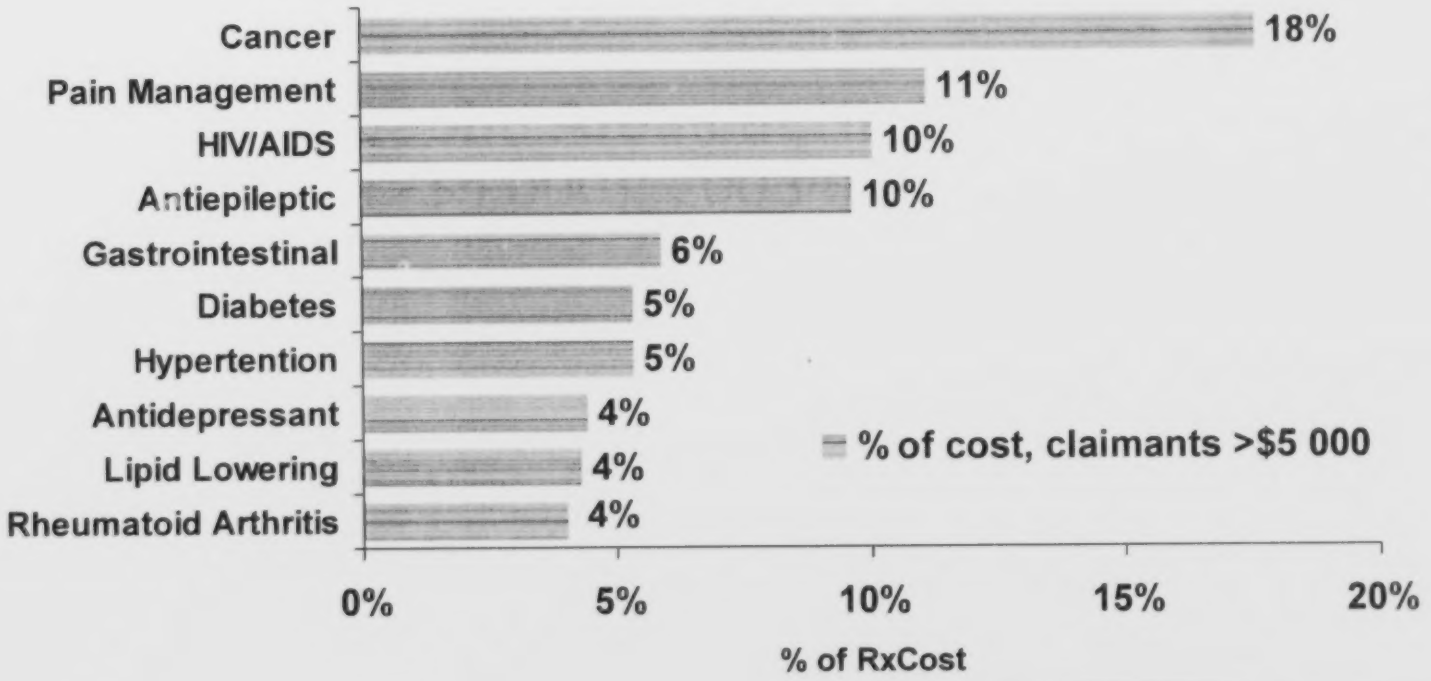
Cost Concentration, From Most to Least Costly Beneficiary, 2003/04



Trend in Cost Concentration
1993/94-2003/04



Top Therapeutic Areas in High Cost Claimants (>$5,000), 2003/04



Highlights of Overview

- Drugs are the fastest growing component of healthcare spending, but still represent just 10% of public expenditures.
- In past years, there was a large decline of beneficiaries covered under MCSS programs, while the number of seniors covered under MOHLTC kept growing.
- Cardiovascular drugs account for a third of total program expenditures, which is related to the prevalence of heart problems.
- A small portion (10%) of beneficiaries account for a large proportion of expenditures (40%).

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Process and Type of Listing

IV. Achievements

Accomplishments and Looking Ahead

Definitions

- Drug cost = Cost at formulary prices
- Markup = Pharmacy Markup + Wholesale Markup
- RxCost = Drug cost + Markup + Dispensing fee
- Gov't cost = Drug cost + Markup + Dispensing fee – Recipient Cost
- Figures includes MOH and MCSS programs unless otherwise specified.

ODB Financial Statistics
2002/03-2003/04

	2002/03	2003/04	Change
Drug Cost	$2,131M	$2,391M	12%
+ Markup	$ 196M	$ 216M	10%
+ Dispensing Fee	$ 393M	$ 444M	13%
= RxCost	$2,720M	$3,051M	12%

	2002/03	2003/04
Markup, as % of total Drug Cost	**8.4%**	**8.3%**
Est. % of cost-to-operator claims	**16%**	**18%**

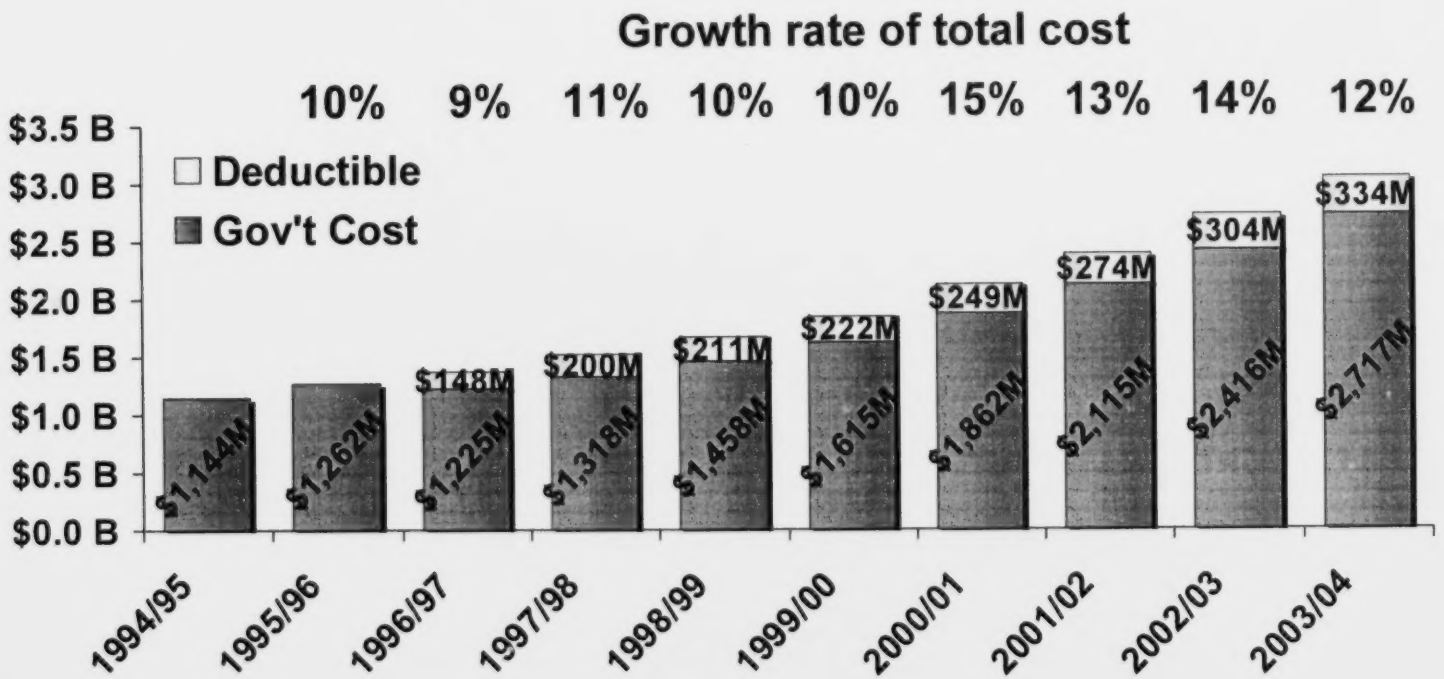
ODB Financial Statistics
2002/03-2003/04

	2002/03	2003/04	Change
Drug Cost	$2,131M	$2,391M	12%
+ Markup	$ 196M	$ 216M	10%
+ Dispensing Fee	$ 393M	$ 444M	13%
= RxCost	$2,720M	$3,051M	12%
- Deductible	$ 304M	$ 334M	10%
= Government Cost	$2,416M	$2,717M	12%
MOHLTC	*$ 1,925M*	*$ 2,167M*	*13%*
MCSS	*$ 491M*	*$ 550M*	*12%*

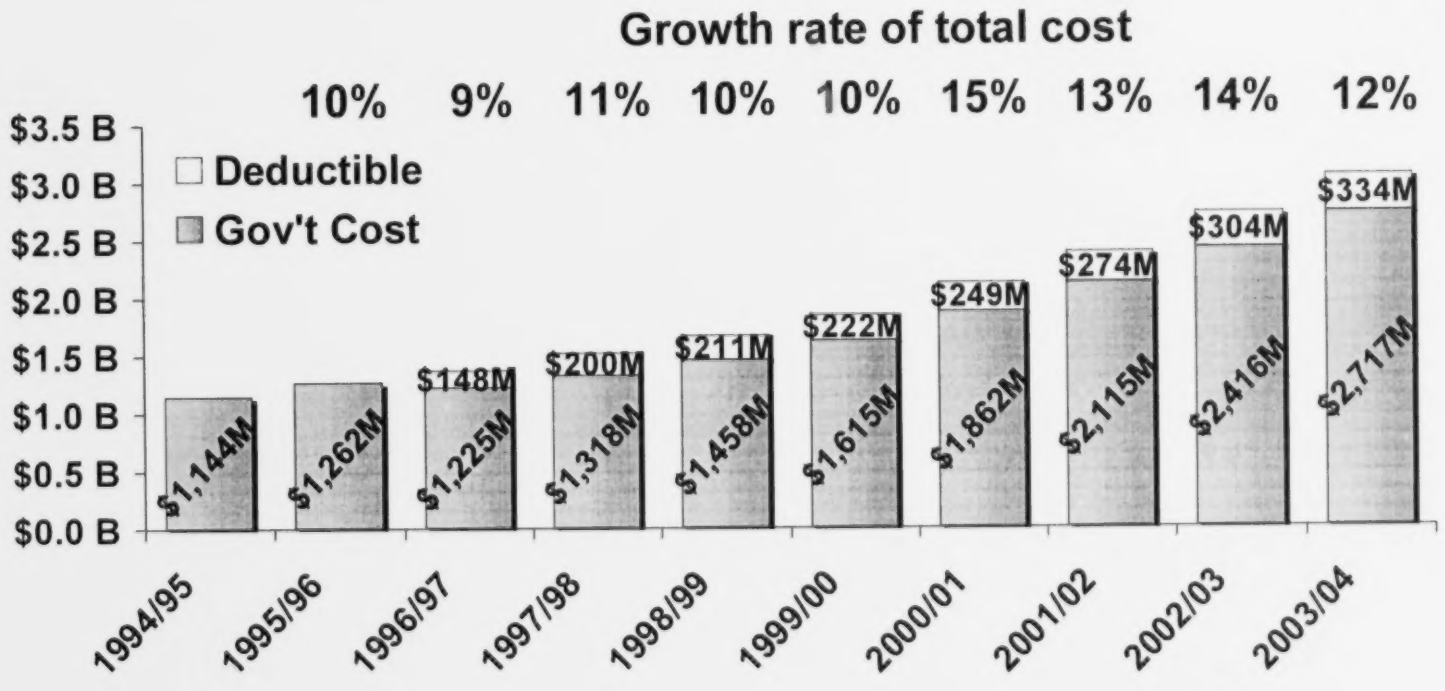
ODB Financial Statistics
2002/03-2003/04

	2002/03	2003/04	Change
RxCost	$2,720M	$3,051M	12%
Brand	*$ 2,078M*	*$ 2,316M*	*11%*
Generic	*$ 642M*	*$ 735M*	*14%*
Beneficiaries	2.08M	2.12M	2%
RxCost/Beneficiary	$ 1,306	$ 1,440	10%
RxCost/Claim	$ 43.63	$ 43.59	0%
Claims/Beneficiary	29.9	33.0	10%

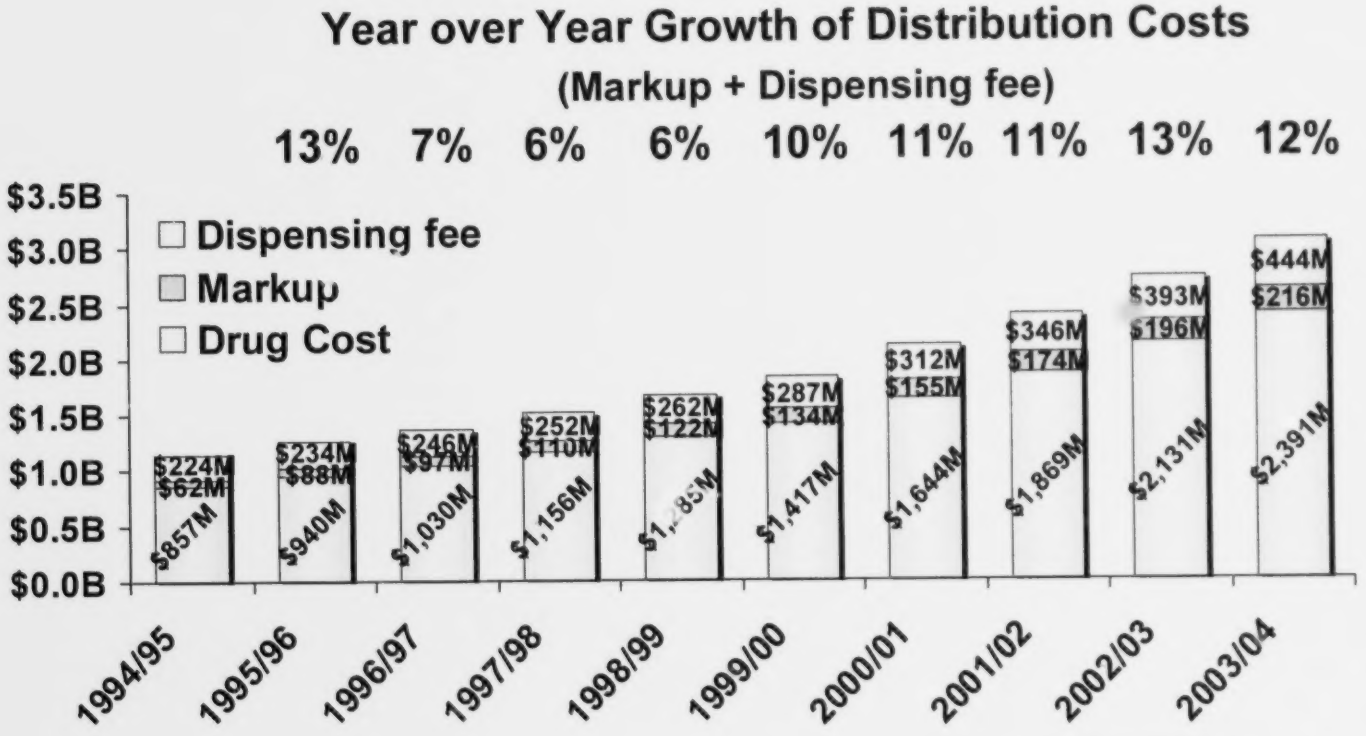
Government & Beneficiary Cost
1994/95-2003/04



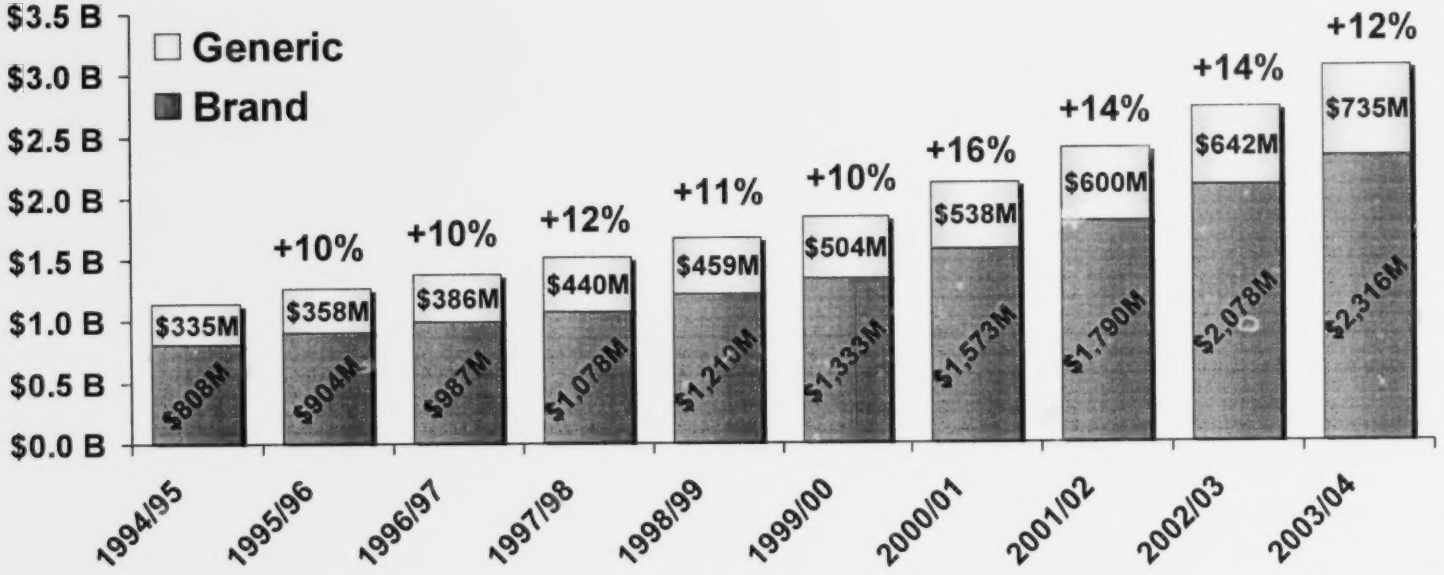
Government & Beneficiary Cost
1994/95-2003/04



Total Cost by Type of Spending
1994/95-2003/04

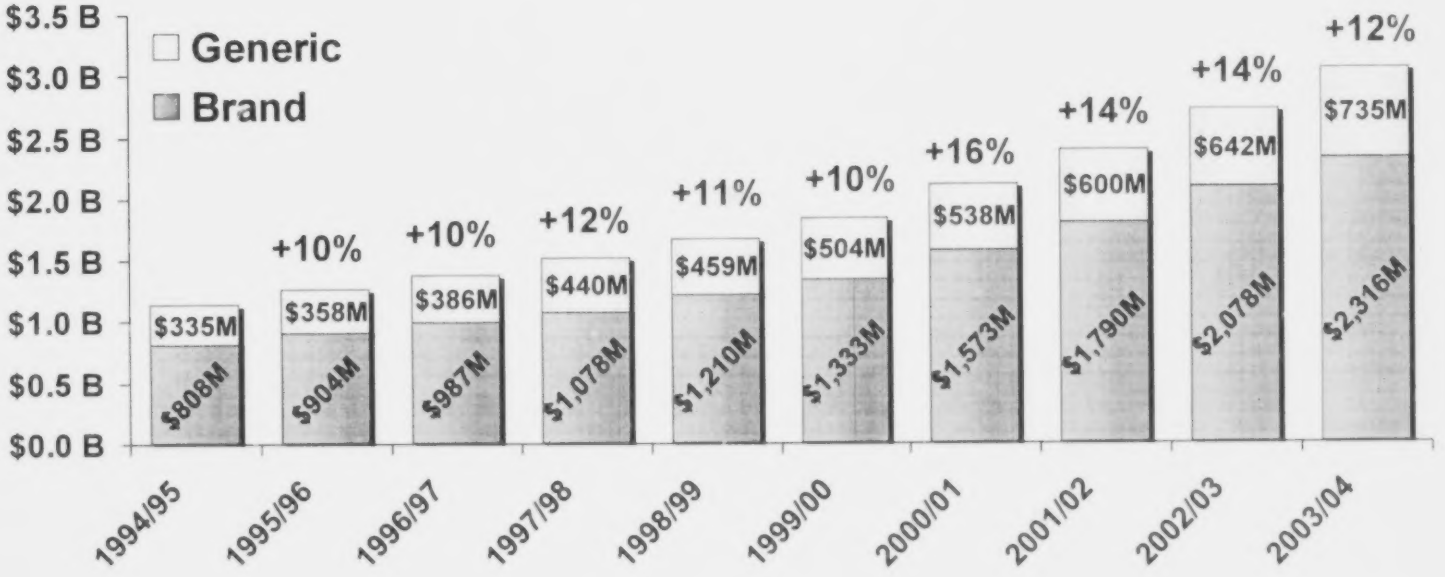


Brand vs. Generic RxCost
1994/95-2003/04



Note: Figures are approximations. Extemporaneous compounds were classified as generics. They accounted for approx. $25.2 million in 2003/04.

Brand vs. Generic RxCost
1994/95-2003/04



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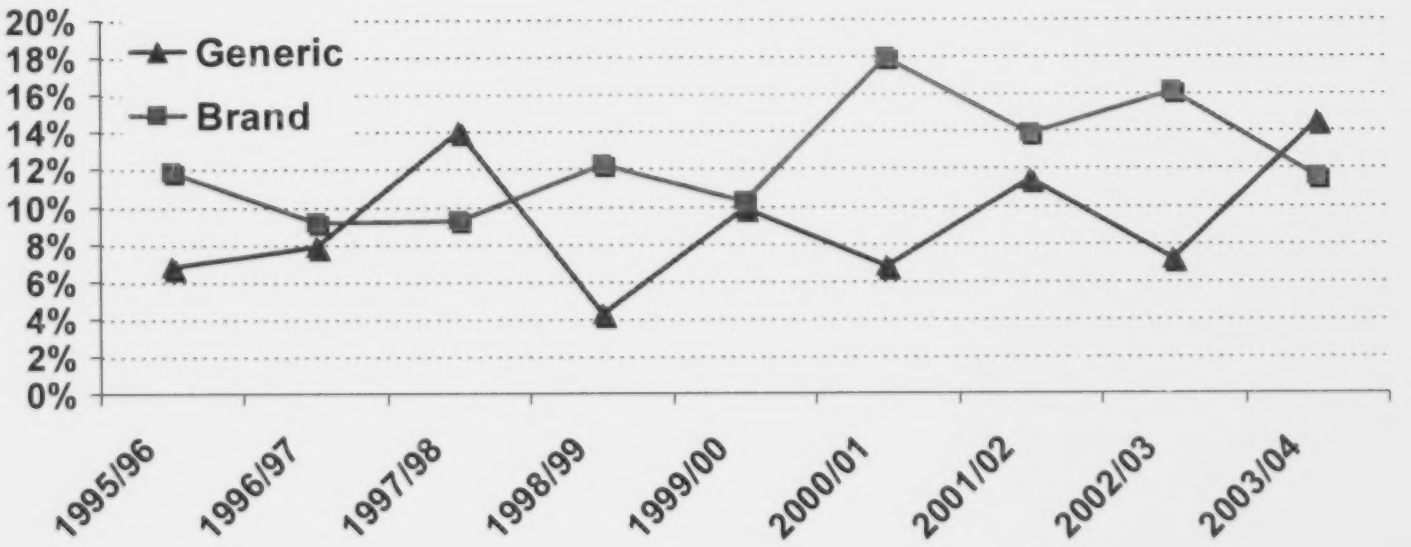
Ministry of Health and Long-Term Care

Brand vs. Generic RxCost
Annual Growth, 1995/96-2003/04

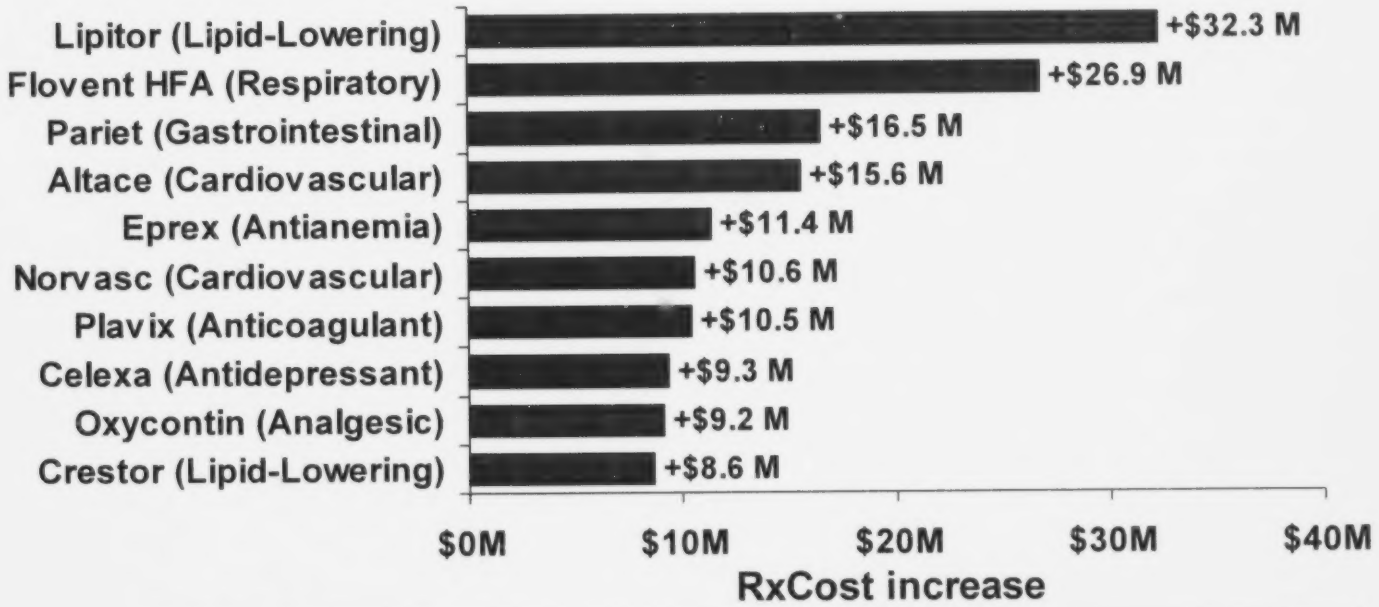


Note: Figures are approximations. Pharmacy compounded products were classified as generics. They accounted for approx. $25.2 million in 2003/04.

Top-10 Chemicals by Drug Cost, 2003/04

Rk	Drug Name	Class	Drug Cost	% Total Drug Cost
1	Atorvastatin (Lipitor)	Lipid-Lowering	$170 M	7.1%
2	Omeprazole (Losec) - LU	Gastrointestinal	$100 M	4.2%
3	Amlodipine besylate (Norvasc)	Cardiovascular	$86 M	3.6%
4	Ramipril (Altace)	Cardiovascular	$80 M	3.3%
5	Olanzapine (Zyprexa)	Anti-psychotic	$68 M	2.9%
6	Diagnostic Agent – Diabetes	Diagnostic Agents	$68 M	2.8%
7	Simvastatin (Zocor)	Lipid-Lowering	$63 M	2.6%
8	Enalapril Maleate (Vasotec)	Cardiovascular	$42 M	1.8%
9	Diltiazem HCl (Tiazac)	Cardiovascular	$40 M	1.7%
10	Donepezil HCl (Aricept) - LU	Autonomic Agents	$38 M	1.6%
TOTAL Top-10			$755 M	32%

Fastest Growing Brand Products
RxCost, 2002/03-2003/04



10 products = 46% of total increase (vs. 45% in 2002/03)

Top-10 Products* Launched Since 2000, by Drug Cost, 2003/04

Rk	Drug Name	Class	Drug Cost	% Total Drug Cost
1	Fluticasone Propionate (Flovent HFA)	Respiratory	$31.1M	1.31%
2	Simvastatin (Apo-Simvastatin)	Antilipemic	$29.0M	1.21%
3	Simvastatin (Gen-Simvastatin)	Antilipemic	$28.0M	1.17%
4	Meloxicam (Mobicox)	Analgesic	$21.0M	0.88%
5	Pravastatin Sodium (Apo-Pravastatin)	Antilipemic	$17.4M	0.73%
6	Rabeprazole Sodium (Pariet)	Gastrointestinal	$16.3M	0.68%
7	Alendronate Sodium (Fosamax) – LU	Other	$12.1M	0.51%
8	Infliximab (Remicade) – Section 8	Immunosupressant	$10.9M	0.46%
9	Imatinib Mesylate (Gleevec) – Section 8	Cancer	$9.4M	0.39%
10	Etanercept (Enbrel) – Section 8	Immunosupressant	$8.5M	0.36%
TOTAL Top-10			$183.7M	7.70%

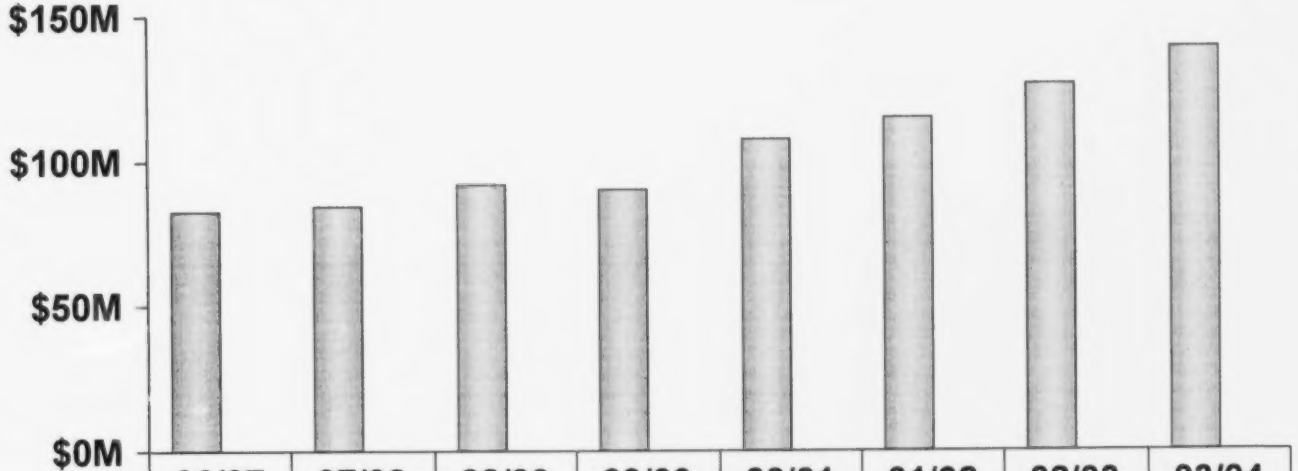
** This analysis includes all generic and brand products launched since 2000*

Top-10 Brand Products* Launched Since 2000, by Drug Cost, 2003/04

Rk	Drug Name	Class	Drug Cost	% Total Drug Cost
1	Fluticasone Propionate (Flovent HFA)	Respiratory	$31.1M	1.31%
2	Meloxicam (Mobicox)	Analgesics	$21.0M	0.88%
3	Rabeprazole Sodium (Pariet)	Gastrointestinal	$16.3M	0.68%
4	Infliximab (Remicade) – Section 8	Immunosupressant	$10.9M	0.46%
5	Imatinib Mesylate (Gleevec) – Section 8	Cancer	$9.4M	0.39%
6	Etanercept (Enbrel) – Section 8	Immunosupressant	$8.5M	0.36%
7	Galantamine Hydrobromide (Reminyl) - LU	Alzheimer's Disease	$8.1M	0.34%
8	Tiotropium Bromide Monohydrate (Spiriva)	Autonomic	$7.2M	0.30%
9	Rosuvastatin Calcium (Crestor)	Antilipemic	$7.2M	0.30%
10	Rivastigmine (Exelon)	Autonomic	$6.8M	0.28%
TOTAL Top-10			$126.5M	5.31%

** This analysis includes all brand products launched since 2000*

Special Drugs Program Cost
1996/97-2003/04



	96/97	97/98	98/99	99/00	00/01	01/02	02/03	03/04
Cost ($M)	82.6M	84.0M	91.5M	90.2M	107.3M	114.6M	126.5M	139.3M
Change	10.9%	1.7%	9.0%	-1.4%	18.8%	6.8%	10.4%	10.1%

Highlights of Financials

- Government share per beneficiary is $1,283, a 11% increase over 2002/03
- The average RxCost per claim remained stable at $43.59, but the number of claims per beneficiary went up 10% to 33.
- The 10 fastest growing products accounted for 46% of the total cost increase.
- $660M went to pharmacies (in fees and mark-ups) while beneficiaries paid $334M in deductible.

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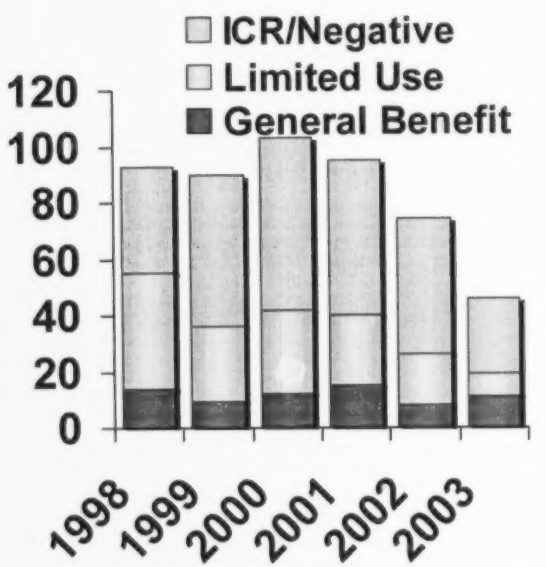
Accomplishments and Looking Ahead

Definitions

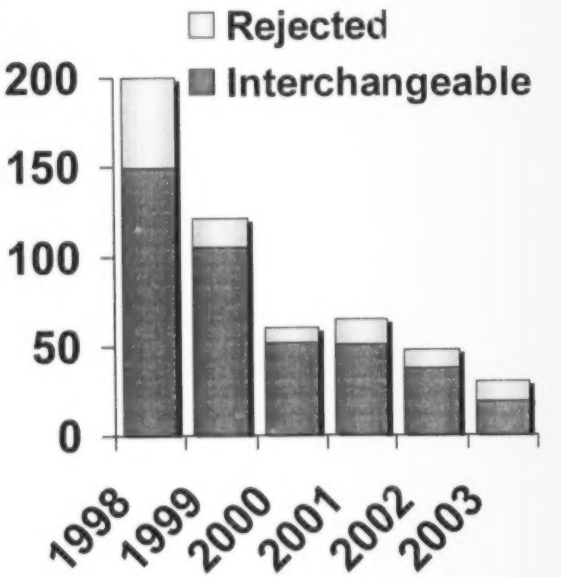
- General Benefit
  - Reimbursement for the drug product is without restrictions.
- Limited Use Products
  - Reimbursement for certain drugs is dependent on specific clinical criteria.
- Individual Clinical Review (Section 8)
  - Individual requests for coverage of drug products not listed in the formulary are reviewed on a case by case basis.

DQTC Recommendations
First Review, 1998-2003



	1998	1999	2000	2001	2002	2003
ICR/Negative	38	54	61	55	48	27
Limited Use	41	27	30	25	18	8
General Benefit	14	9	12	15	8	11

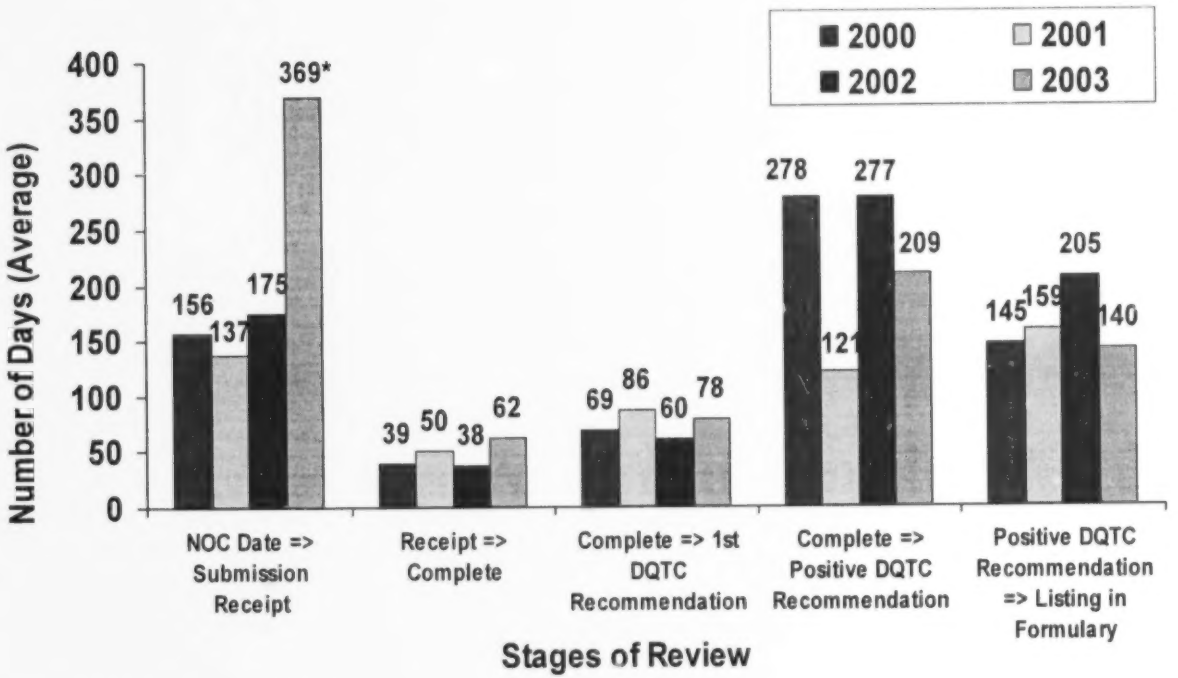
Single Source



	1998	1999	2000	2001	2002	2003
Rejected	51	16	8	14	10	11
Interchangeable	149	105	52	51	38	19

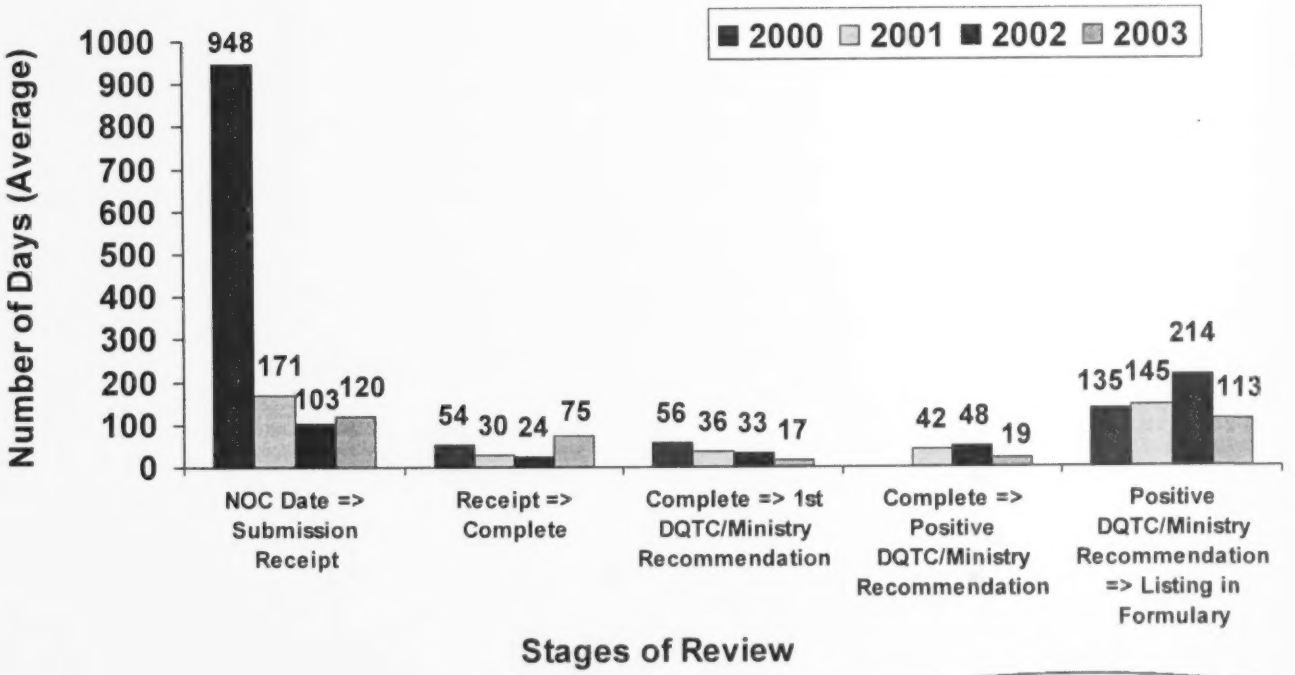
Multiple Source

Average Review Timelines for All Single Source Drug Products Listed in 2003

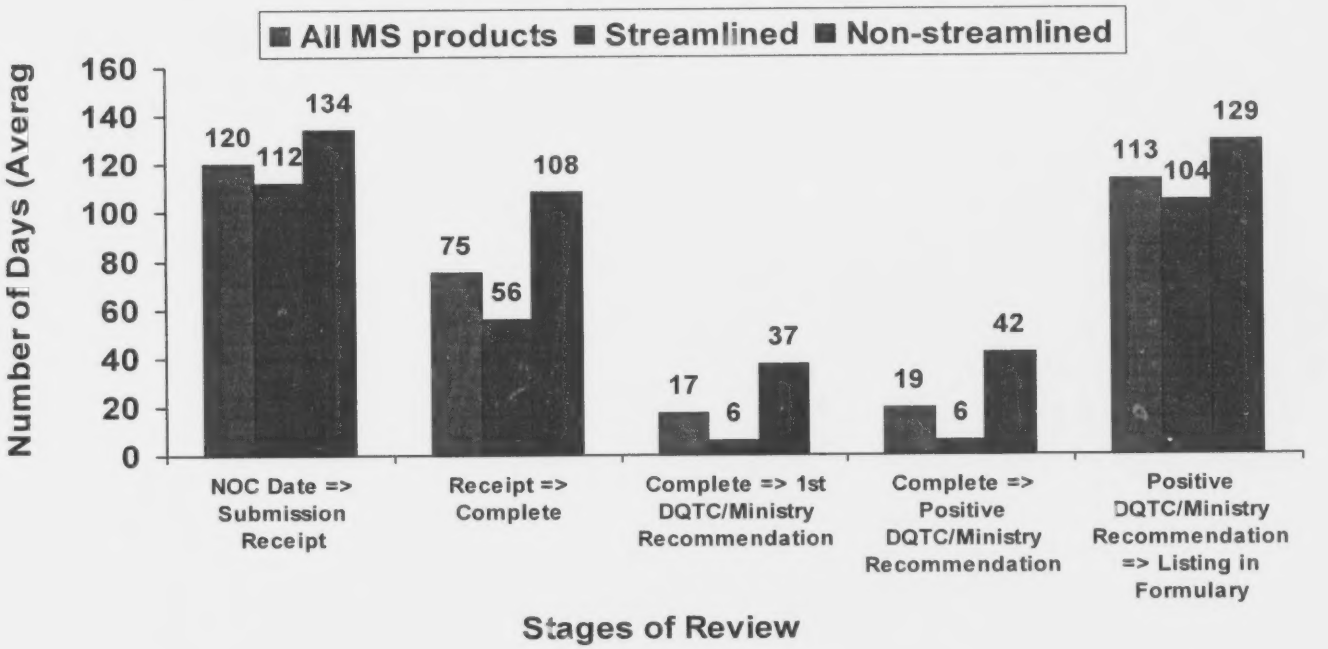


* 6 products had significant lag time from NOC receipt to submission

Average Review Timelines for All Multiple Source Drug Products Listed in 2003

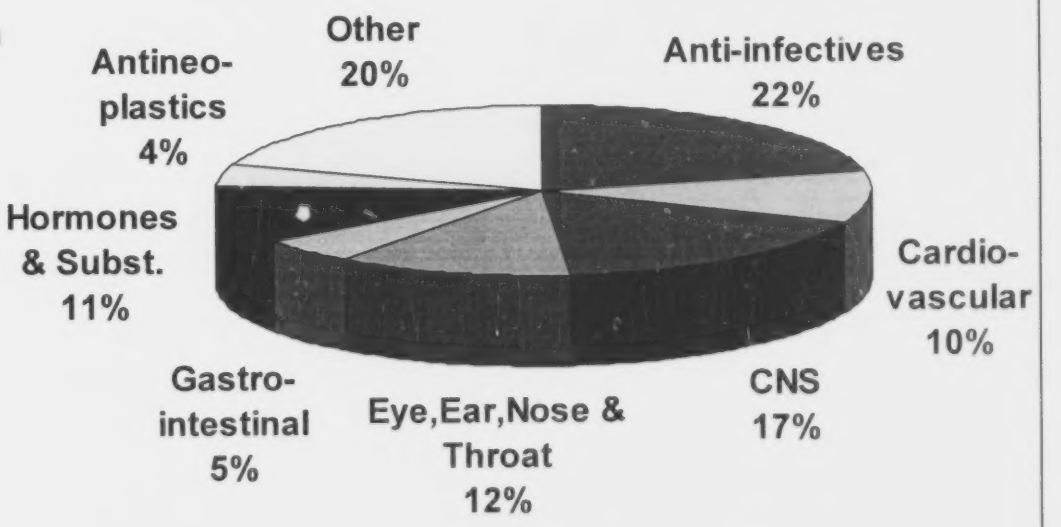


Streamlined vs Non-Streamlined Multiple Source Drug Products Listed in 2003



Written Agreements by Therapeutic Class, 2003/04

- Forecasted cost provided by manufacturers for each of the first three years of new single-source drugs listed
- 171 agreements have been signed as of Formulary 38, Update B

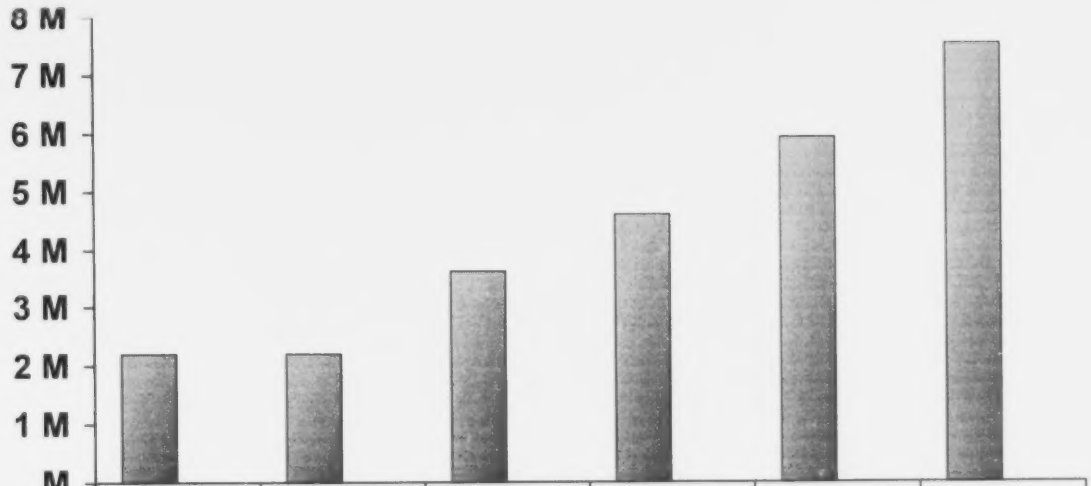


Top-10 Chemicals, by Number of Claimants (thousands), 2003/04

Rk	Drug Name	Class	Claimants	% Claimants
1	Acetaminophen & Cafeine & Codeine (Tylenol No.3)	Analgesic	413 K	19.5%
2	Atorvastatin (Lipitor)	Lipid-Lowering	326 K	15.4%
3	Amoxicillin	Antibiotic	310 K	14.6%
4	Ramipril (Altace)	Cardiovascular	298 K	14.1%
5	Hydrochlorothiazide	Diuretic	272 K	12.8%
6	Levothyroxine sodium (Synthroid)	Hormones	244 K	11.5%
7	Lorazepam (Ativan)	Central Nervous System	241 K	11.4%
8	Ranitidine HCl (Zantac)	Gastrointestinal	227 K	10.7%
9	Diagnostic Agents - Diabetes	Diabetes	224 K	10.6%
10	Acetylsalicylic Acid	Analgesic	219 K	10.3%

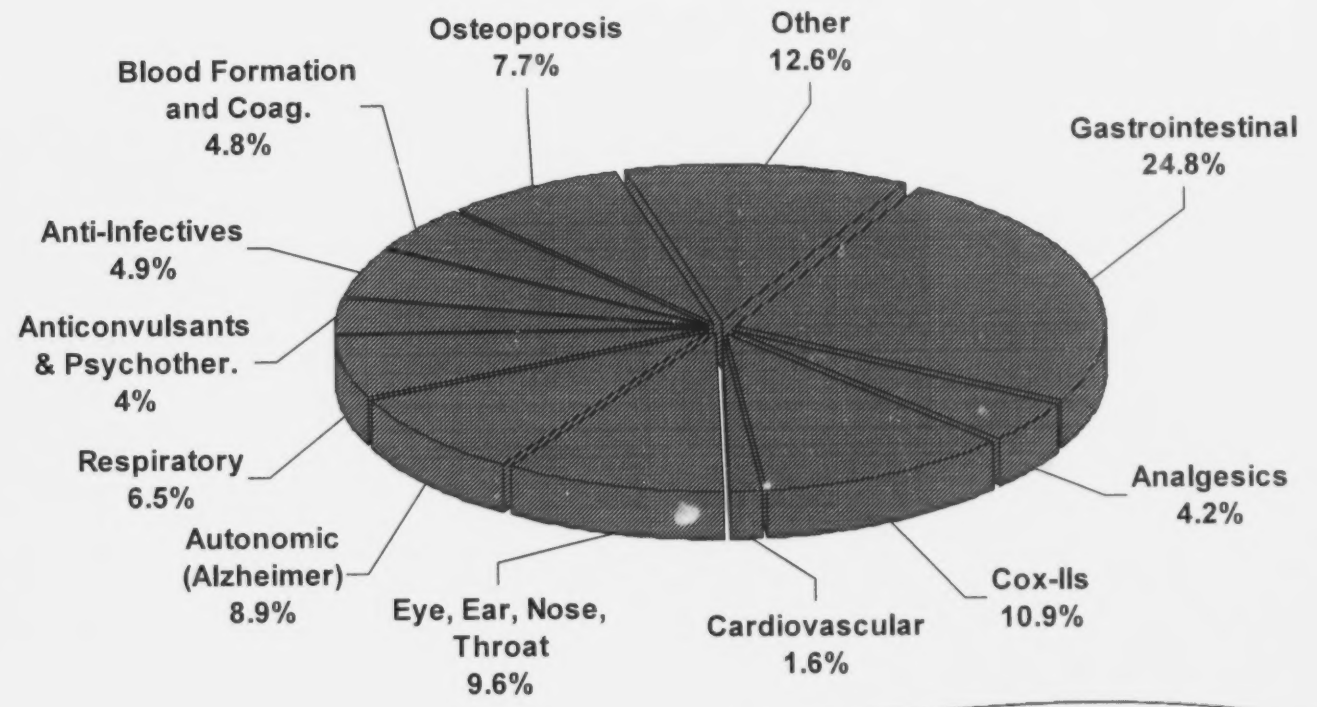
All these drugs are General Benefits

Limited Use Products
Number of Claims, 1998/99-2003/04



	1998/99	1999/00	2000/01	2001/02	2002/03	2003/04
Claims (million)	2.2 M	2.2 M	3.6 M	4.6 M	5.9 M	7.5 M
% of Overall ODB	4.9%	4.8%	7.2%	8.3%	9.4%	10.7%

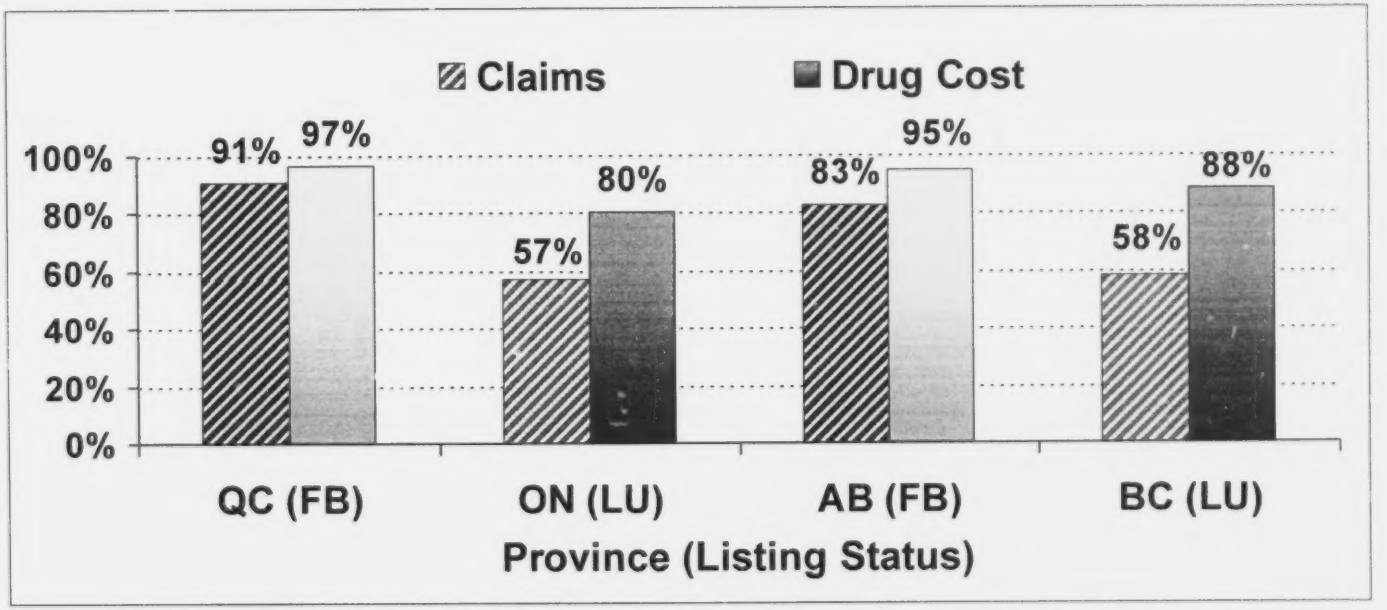
Limited Use Products
Claims by Class, 2003/04



Ministry of Health and Long-Term Care

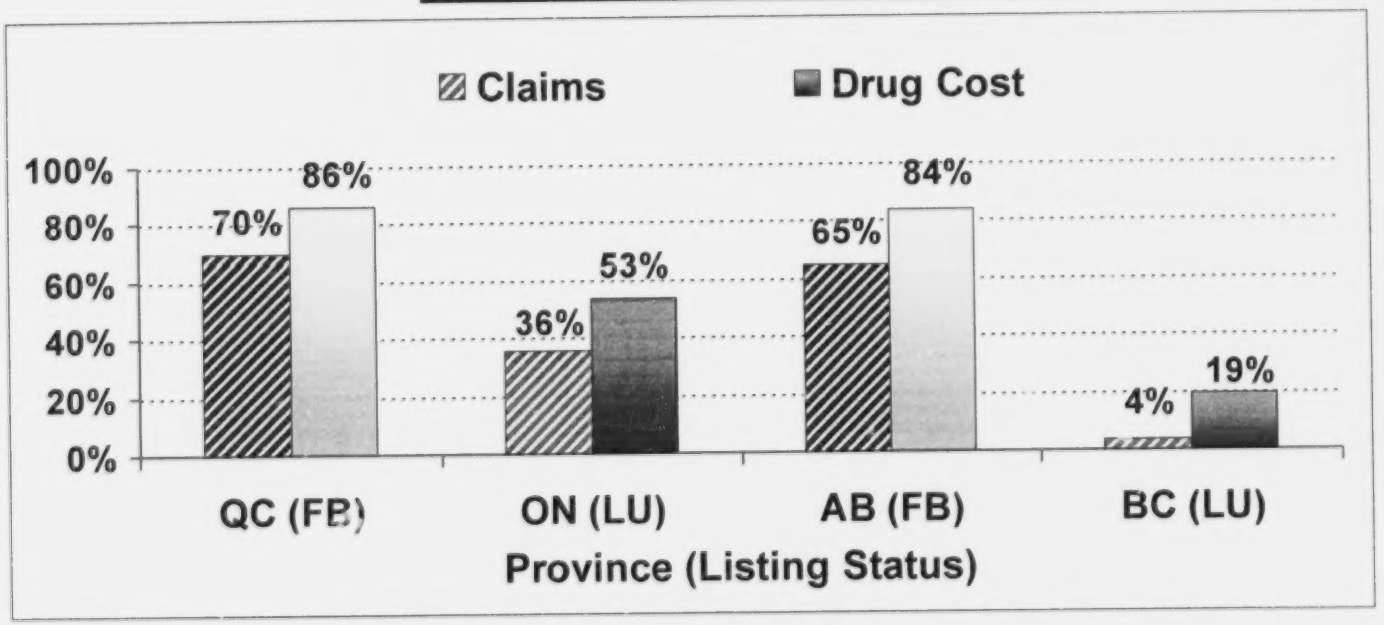
Limited Use Products vs. Entire Class, by province, 2003

Proton Pump Inhibitors vs. Class*



*The class is defined as Proton Pump Inhibitors and Histamine H2 Receptor Antagonists.

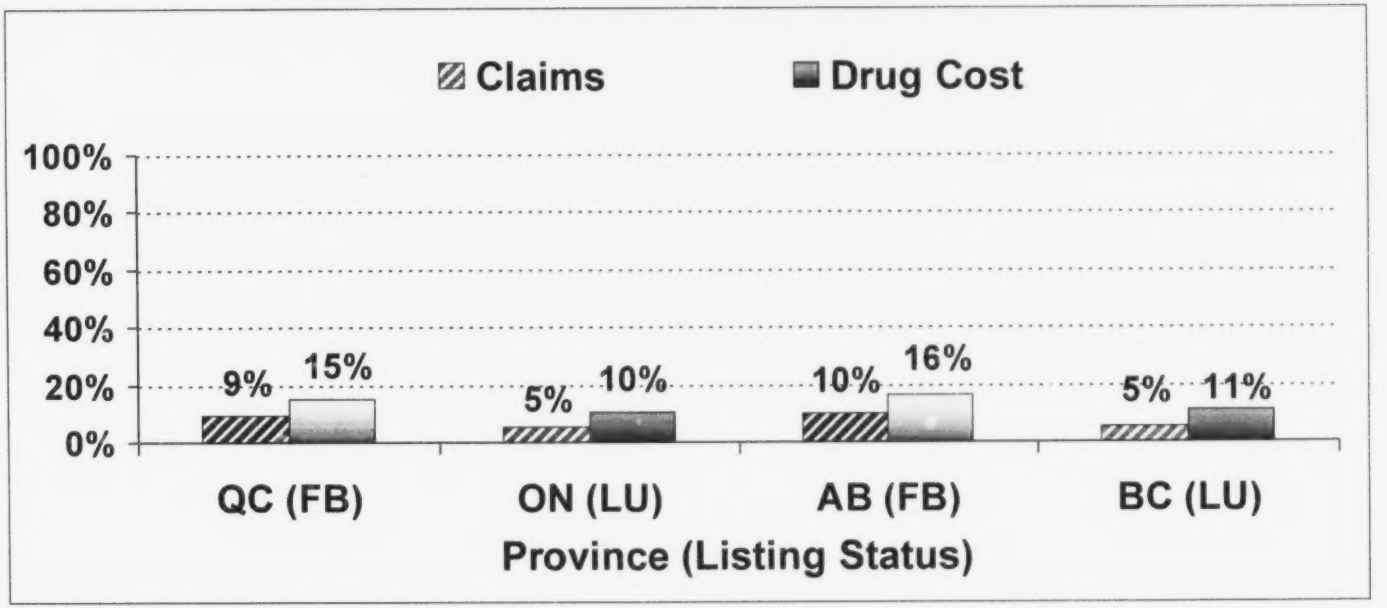
Limited Use Products vs. Entire Class, by province, 2003



*The Limited Use drugs are Celebrex and Vioxx. The class is all Non-Steroidal Anti-Inflammatory Drugs (excluding ASA).

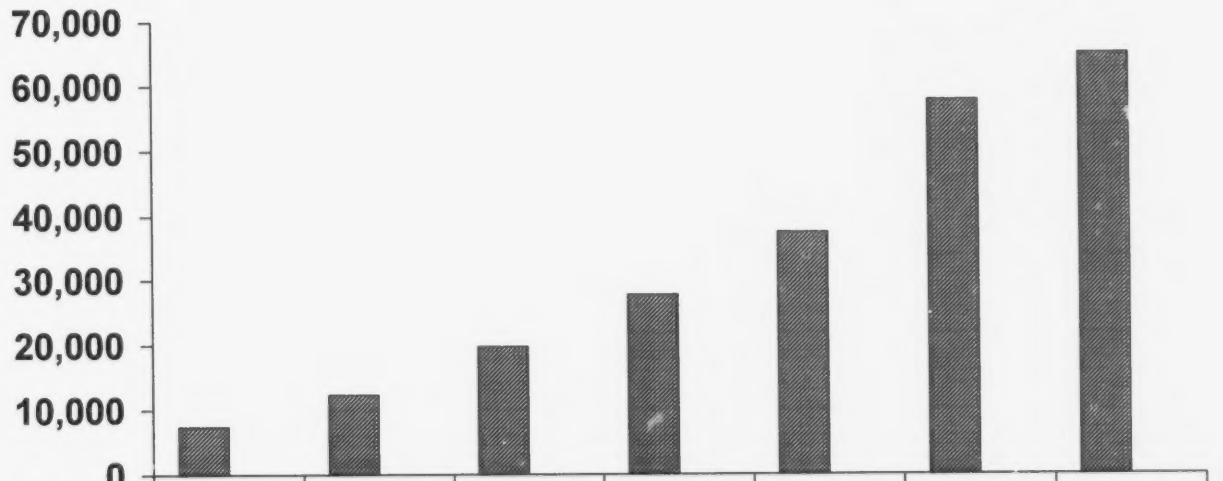
Limited Use Products vs. Entire Class, by province, 2003

Angiotensin II Antagonists vs. Class*



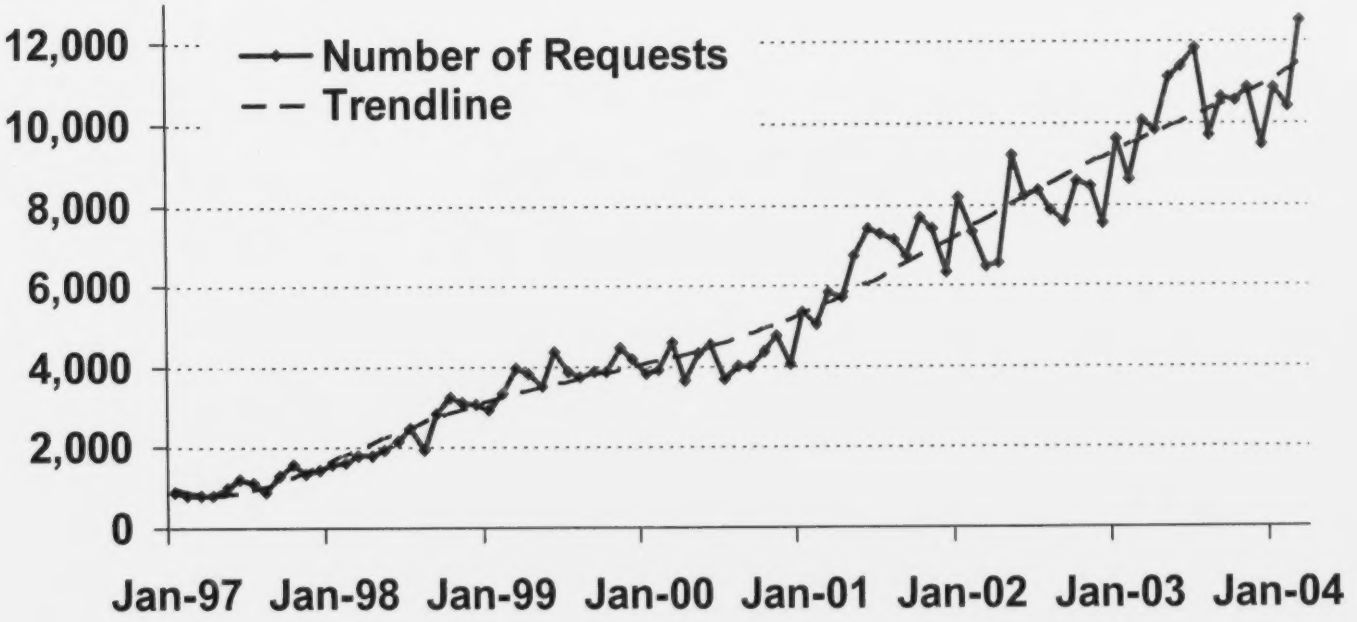
*The class is defined as Angiotensin II Antagonists, Ace-Inhibitors, Calcium Channel Blockers, Diuretics and Beta Blockers.

Individual Clinical Review Beneficiaries, 1997/98-2003/04



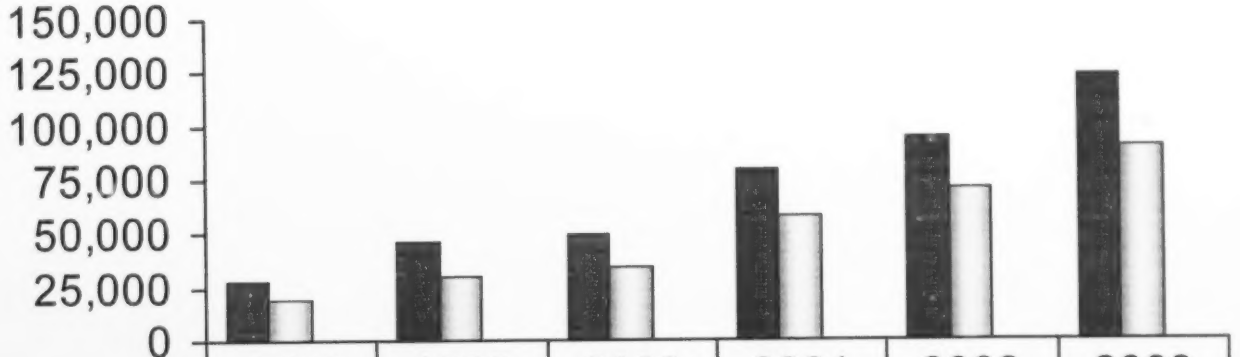
	1997/98	1998/99	1999/00	2000/01	2001/02	2002/03	2003/04
Beneficiaries	7,429	12,401	19,818	27,848	37,303	57,754	64,905
% of Overall ODB	0.3%	0.6%	0.9%	1.3%	1.8%	2.8%	3.0%

Monthly ICR Requests
January 1997-March 2004



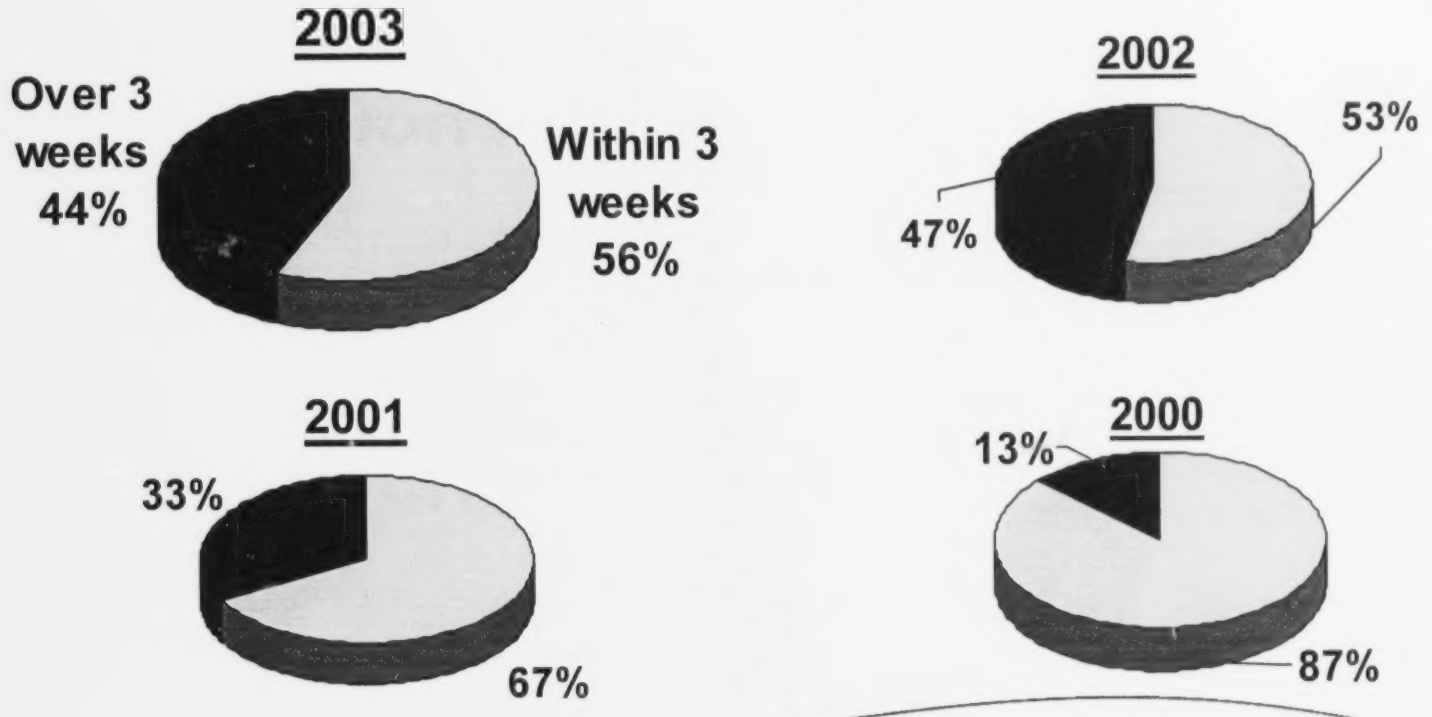
Ministry of Health and Long-Term Care

ICR Requests & Approval Rate 1998-2003



	1998	1999	2000	2001	2002	2003
■ Received	27,472	45,694	49,518	78,855	94,212	123,515
□ Approved	18,924	30,487	34,110	57,628	70,907	90,095
% Increase	108%	66%	8%	59%	19%	31%
% Approved	**69%**	**67%**	**69%**	**73%**	**75%**	**73%**

ICR Response Time
2000-2003



ICR Top-10 Requested Drugs, 2003/04

Rk	Drug	Requests	Approved	% Approved	Gov't Cost
1	Plavix	41,936	36,339	86.7%	$24.4M
2	Avandia	12,748	8,941	70.1%	$5.0M
3	Eprex	7,404	4,893	66.1%	$12.9M
4	Actos	5,708	4,334	75.9%	$3.0M
5	Pegetron	3,079	2,167	70.4%	$6.0M
6	Remicade	3,403	2,703	79.4%	$10.7M
7	Gabapentin	3,066	2,139	69.8%	$0.8M
8	Neupogen	2,417	1,692	70.0%	$5.8M
9	GlucoNorm	1,944	1,143	58.8%	$0.2M
10	Singulair	1,610	942	58.5%	$0.6M
Top-10 Total		83,315	65,293	78.4%	$69.4M

ICR, Top-10 Drugs
by Government Cost, 2003/04

Rk	Drug	Beneficiaries	Rx	Gov't Cost
1	Plavix	33,357	253,523	$24.4M
2	Eprex	1,430	6,376	$12.9M
3	Remicade	682	3,115	$10.7
4	Gleevec	347	2,231	$9.4
5	Enbrel	705	5,825	$8.7
6	Rebif	412	3,542	$6.2
7	Pegetron	600	4,078	$6.0
8	Neupogen	891	3,160	$5.8
9	Avandia	6,361	34,967	$5.0
10	Sandostatin	322	2,754	$4.5
Total Top 10 Section 8		45,107	319,571	$93.6M
% Top 10 Section 8 / Total Section 8 FY 2003/04		69.6%	69.9%	70.7%

Highlights of Formulary

- In 2003, the DQTC recommended the listing of 19 single-source products, 11 as General Benefits and 8 as Limited Use Benefits.
- The average time from the receipt of a complete single source drug submission to Formulary listing was 427 days in 2003.
- The top 10 drugs by the number of recipients receiving therapy are all General Benefit.
- The number of Limited Use claims has quadrupled in the past five fiscal years.
- 123,515 requests were processed through the Individual Clinical Review mechanism in 2003, and 73% of those requests were approved.

Report Card Framework

I. Program Overview

Program overview and utilization trends

II. Financial

Financial indicators and cost trends

III. Formulary Listings

Product and Type of Listing

IV. Achievements

Accomplishments and Looking Ahead

Formulary Updates

- Edition 38 Update A - Apr 16, 2003
  - 53 drug product additions, 10 nutrition products
- Edition 38, Update B - Sept 4, 2003
  - 47 drug product additions, 4 nutrition products, 2 diabetic testing agents
  - Plavix listed as a Limited Use Benefit
  - changes to intravenous extemporaneous solutions
  - streamlining of Report C products
- Edition 38, Update C - Apr 6, 2004
  - 109 drug product additions, 2 nutrition products
  - A2RBs moved to General Benefit

Drug Coverage

- 2003 Health Accord includes catastrophic drug coverage
- Commitment that "Canadians should not suffer undue financial hardship for needed drug therapy"
- Ontario already provides catastrophic drug coverage through the Trillium Drug Program.
- F/P/T work focused on broad definitions, principles and performance indicators.
- Income testing drug coverage for seniors considered and rejected by Government.

Drug Strategy Review

- Steering Committee and 4 working groups debated issues, considered public submissions, research reports and policy papers.
  - cost-effectiveness and pricing of drugs
  - drug prescribing and use
  - program administration
  - drug distribution and reimbursement
- Multi-stakeholder conference on medication management opportunities held.
- Interim report completed by Steering Committee and submitted to Minister.

Medication Management

- F/P/T work to develop Canadian Optimal Prescribing and Utilization Service (COMPUS)
- Priorities for COMPUS are proton pump inhibitors, diabetes, and hypertension
- Ontario explored ways to support improved medication management through:
  - integration of pharmacists into primary care group practices
  - provision of easily accessible, independent sources of evidence-based information
  - electronic medication profiles for prescribers and pharmacists
  - participation in work of Institute for Safe Medication Practices

Drug Review Process

Common Drug Review

- Chaired CEDAC nomination process
- Developed process for integration of permanent CDR process into DPB/DQTC's process
- Active participation at national level on CDR Committee (CDRC)
- Monitored timelines for CDR and CEDAC recommendations to ensure both meet Ontario's needs

Modernization Reviews

- Completed glaucoma and diabetes
- HRT and testosterone on-going

Generic Streamlining

- Participated in F/P/T committee on generic streamlining
- Streamlined Report C products
- CGPA Workshop held to discuss submission requirements for aqueous solutions

Stakeholder Relations

- Regular meetings with pharmaceutical manufacturers and associations;
- Regular meetings with Ontario Pharmacists Association on pharmacy directions;
- Meetings with Limited Use Tripartite Committee, Physician Services Committee, Drugs & Pharmacotherapy Committee;
- Meetings with Canadian Life & Health Insurance Associations and private insurers
- Information sessions held with pharmacists and physicians regarding sample communication tools
- Workshops held with Rx&D, CGPA

Looking Ahead

- Pharmaceuticals Strategy – national and provincial initiatives
- Formulary Modernization – class reviews, Limited Use, section 8, post-marketing evaluations
- Medication Management – DQTC communications, pharmacists in family health teams, focus on chronic diseases
- Drug Pricing – purchasing and policy options for patented and non-patented drugs
- E-Pharmacy – all drugs all people, medication profiles, prescribing